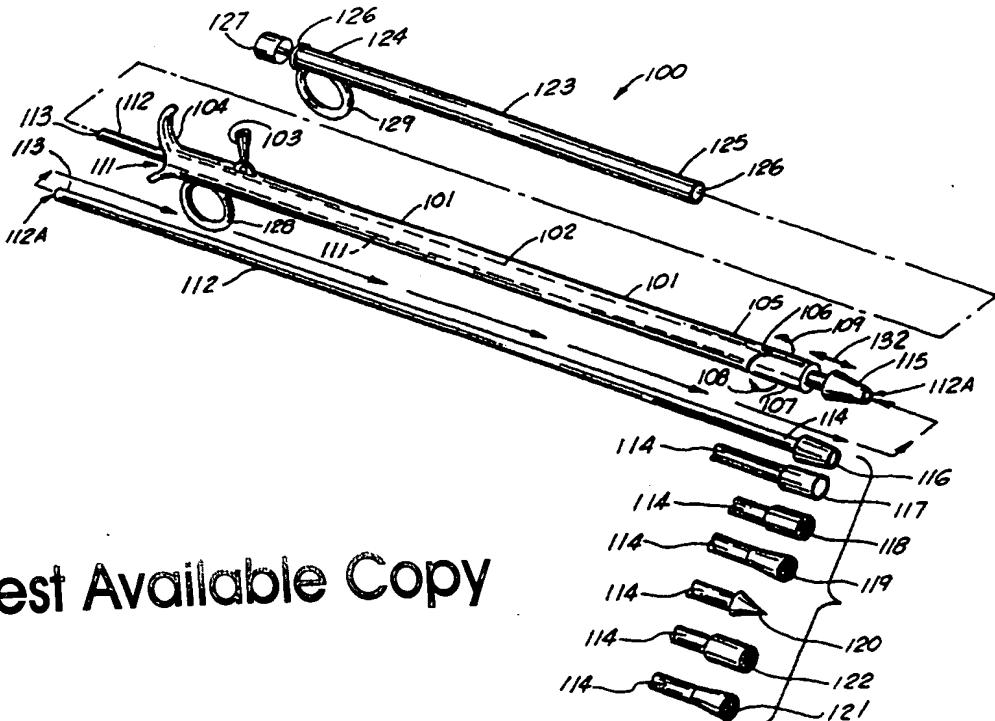




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | | | | | | | | | | | |
|--|------------------------------|------------|---|----|------------|------------------------|----|------------|------------------------------|----|--|--|
| (51) International Patent Classification 6 : A61M 5/00 | | A1 | (11) International Publication Number: WO 97/36622 (43) International Publication Date: 9 October 1997 (09.10.97) | | | | | | | | | |
| <p>(21) International Application Number: PCT/US97/05397</p> <p>(22) International Filing Date: 1 April 1997 (01.04.97)</p> <p>(30) Priority Data:</p> <table> <tr> <td>08/625,098</td> <td>1 April 1996 (01.04.96)</td> <td>US</td> </tr> <tr> <td>08/644,504</td> <td>10 May 1996 (10.05.96)</td> <td>US</td> </tr> <tr> <td>08/718,861</td> <td>24 September 1996 (24.09.96)</td> <td>US</td> </tr> </table> <p>(71) Applicant (for all designated States except US): SYNECHION/TILTON JOINT VENTURE (a joint venture of SYNECHION, INC. and TILTON, EUGENE, B., JR.) [US/US]; Suite 508, 15775 Hillcrest Road, Dallas, TX 75248 (US).</p> <p>(72) Inventor; and</p> <p>(75) Inventor/Applicant (for US only): TILTON, Eugene, B., Jr. [US/US]; 513 Dorrington Boulevard, Metairie, LA 70005 (US).</p> <p>(74) Agents: GARVEY, Charles, C., Jr. et al.; Pravel, Hewitt, Kimball & Krieger, 10th floor, 1177 West Loop South, Houston, TX 77027 (US).</p> | | 08/625,098 | 1 April 1996 (01.04.96) | US | 08/644,504 | 10 May 1996 (10.05.96) | US | 08/718,861 | 24 September 1996 (24.09.96) | US | <p>(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p> | |
| 08/625,098 | 1 April 1996 (01.04.96) | US | | | | | | | | | | |
| 08/644,504 | 10 May 1996 (10.05.96) | US | | | | | | | | | | |
| 08/718,861 | 24 September 1996 (24.09.96) | US | | | | | | | | | | |
| <p>(54) Title: INSTRUMENTATION FOR SURGICAL ENDOSCOPIC INSERTION AND APPLICATION OF LIQUID, GEL AND LIKE MATERIAL</p> <p>(57) Abstract</p> <p>A method and apparatus for laparoscopic insertion and application of a liquid, gel or medicinal material enables the laparoscopic surgeon to utilize various spray patterns to apply the desired material. In laparoscopy surgery of the abdomen (including pelvis), all instrumentation and all surgical products must be introduced through "ports" consisting of valved, sleeved or tubes. To properly and efficiently introduce and apply liquid, gel or medicinal material, the present invention provides a method and apparatus for dispensing the desired material with a desired spray or pattern. The instrument consists of an elongated instrument body (20) that can receive a selected flexible delivery tube (21) having a distal end with a nozzle (116-121). The instrument body articulates at its distal end, thereby flexing the dispensing tube. The selected nozzle of the selected dispensing tube can be flexed to dispense with a desired spray pattern to a spray head, into any position of the patient's abdominal cavity. A syringe (or a syringe with an extension tube) can be used to push gel or liquid medicine through the dispensing tube (112) to the distal end thereof.</p> | | | | | | | | | | | | |



Best Available Copy

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|----|--------------------------|----|---------------------------------------|----|---|----|--------------------------|
| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav Republic of Macedonia | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | ML | Mali | TR | Turkey |
| BG | Bulgaria | HU | Hungary | MN | Mongolia | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MR | Mauritania | UA | Ukraine |
| BR | Brazil | IL | Israel | MW | Malawi | UG | Uganda |
| BY | Belarus | IS | Iceland | MX | Mexico | US | United States of America |
| CA | Canada | IT | Italy | NE | Niger | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NL | Netherlands | VN | Viet Nam |
| CG | Congo | KE | Kenya | NO | Norway | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NZ | New Zealand | ZW | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's Republic of Korea | PL | Poland | | |
| CM | Cameroon | KR | Republic of Korea | PT | Portugal | | |
| CN | China | KZ | Kazakhstan | RO | Romania | | |
| CU | Cuba | LC | Saint Lucia | RU | Russian Federation | | |
| CZ | Czech Republic | LI | Liechtenstein | SD | Sudan | | |
| DE | Germany | LK | Sri Lanka | SE | Sweden | | |
| DK | Denmark | LR | Liberia | SG | Singapore | | |

5 INVENTION: "INSTRUMENTATION FOR SURGICAL ENDOSCOPIC INSERTION
AND APPLICATION OF LIQUID, GEL AND LIKE MATERIAL"

SPECIFICATION

Cross Reference to Related Applications:

10 This is a continuation of copending U.S. Patent Application Serial No. 08/718,861, filed September 24, 1996, which is a continuation-in-part of copending U.S. Patent Application Serial No. 08/644,504, filed May 10, 1996, which is a continuation-in-part of copending U.S. Patent Application Serial No. 08/625,098, filed April 1, 1996, which is a continuation-in-part of U.S. Patent Application Serial No. 08/407,409, filed March 17, 1995 (now U.S. Patent No. 5,503,623), all incorporated herein by reference.

BACKGROUND OF THE INVENTION:

15 1. Field of the Invention

The present invention relates to a method and apparatus for laparoscopic introduction and application of liquid, gel, and like medicinal materials.

2. General Background

20 Surgery performed within the pelvis and abdomen by means of laparoscopy utilizes of one or more entry "ports" in varying size. The majority of sizes is in the range of five (5) millimeters to fifteen (15) millimeters. Each port consists of a tube with proximal and distal ends. A valve structure on the proximal end of the port member allows instruments to be passed through the abdominal wall while maintaining appropriate intra-abdominal CO₂ pressure.

25 While instruments pass easily through the associated port member and its valve structure, liquids, gels, and like medicinal materials cannot be easily administered in laparoscopic surgery.

In laparoscopy surgery, there are or will be a variety of liquid, gel and like medicinal materials that require application in the abdomen (including the pelvis). Because these products have specific medical purposes (example: adhesion prevention and as a delivery vehicle) the application will have to be precise (to targeted areas or tissues) as opposed to the general way irrigating solutions are administered to wash or rinse tissues during surgery. Also, because these products will be expensive they cannot be wasted and precise application is desired.

Currently, liquids or solutions are usually administered through a common laparoscopy instrument called a suction/irrigator, aspiration/irrigator, irrigator, irrigating cannula, cannula or

other similar terminology. These are simple straight tubes usually ranging from between about 3mm and 5mm in diameter with an opening on the distal end and possibly some holes on the side of the tube near that end.

5 Rinsing or irrigating fluids are flushed in to wash and moisten tissues. These simple tubes (usually metal or plastic) can also administer some liquid medical products though but not with precision or purpose and not in any specific, selected direction or specific, selected pattern. There are also long needles used for injection of medicines or retrieving of eggs from ovaries. However, these are simply an extension of the well-known standard injection needle. Such 10 needles are for injection of liquid and medicines into tissues while the present invention is for applying liquid, gels and like medicinal materials onto the surface of tissues even if these products attach to or ultimately penetrate into the tissues.

SUMMARY OF THE INVENTION:

15 The present invention is designed for a variety of installation requirements and a variety of products. There are a variety of head designs to effect the type of delivery or delivery pattern and pass different product variations. Some of the heads have variously narrowing conical shapes and are designed for gels, liquids and medicines that need application to certain size local spots. Other heads are for dispersion of gels only, enhanced by a combination of shape (straight and widening conical) and the presence of grids. A wide (but not haphazard, wasteful, or 20 harmful) distribution is desired.

20 In a conical head, the grids can be angled outwardly to further cause the gel to disperse more outward to cover even more area when desired. Some of the heads have multiple holes at the end. These are for controlled dispersion of liquids only, with two preferred shapes: straight and widening conical. The conical shape is also for wider dispersion. The holes can also be angled outwardly to cause the liquid to disperse in a wider pattern. These various heads are 25 uniquely designed for particular applications and for various products. The various heads and their associated long flexible portion are all designed to be interchangeable and fit into the main body of the instrument.

30 The distal end of the main body of the instrument can be angled up to 90 degrees in two pivotal directions. When the instrument is manually rotated, this allows aiming of the selected delivery head in virtually any direction to reach any area in the abdomen (including pelvis). This also includes hard to reach areas such as parts of the intestines, the under side of the uterus, behind the ovaries and the entire anterior abdominal wall.

To further reach difficult areas, the inner portion of the main body can be pushed in to move the flexible plastic tube and its applicator head farther into the abdomen to small areas, more distant areas or, most importantly, areas that couldn't otherwise be reached because the main body of the instrument is blocked by other tissues or organs.

5 The instrument overall diameter can vary, probably between about 5 mm and 15 mm with approximately 10 mm being a preferred general size.

The present invention thus provides a method and apparatus for laparoscopic introduction and application of a variety of liquid, gel, and medicinal materials, enabling the surgeon to more efficiently use these materials. In laparoscopy surgery of the abdomen (including pelvis), all 10 instrumentation and all surgical products must be introduced through "ports" consisting of valved sleeves or tubes. To properly and more efficiently introduce and apply a variety of liquids, gels and medicines (such as Sepracoat, Sepragel and Flo-Gel), the present invention provides a method and apparatus for dispensing these products through a flexible tube which can be angled and adjusted to guide them to any site, including hard to reach areas.

15 Interchangeable tubes allow having a variety of heads for different types of dispersement of the liquid, gel, or medicine (examples: pin-point application, broad application, shower - like spray application).

The present invention provides an improved method and apparatus for dispensing liquid medicinal, gel, or like material into a patient's abdomen during a laparoscopy procedure.

20 The method includes the surgical forming of a small opening through the patient's abdominal wall. A first tubular member is placed through this surgical opening, the tubular member having proximal and distal end portions. The second tubular member is then inserted into the bore of the first tubular member and through a valve structure that can be provided if desired on the proximal end of the first tubular member.

25 This allows the surgeon to valve the flow of gases between the patient's abdominal and the proximal end of the first tubular member. The second tubular member defines an instrument body that can be extended into the patient's abdominal cavity.

The surgeon selects a flexible dispensing tube and places it in the bore of the second 30 tubular member or instrument body. This flexible dispensing tube has a distal end with a nozzle for applying a desired liquid, gel or medicinal material to the patient's abdominal cavity with a desired distribution or spray pattern. In the preferred method, there are a plurality of different flexible dispensing tubes, each having a different spray pattern that can be created by differing the number of holes through each nozzle in the direction of orientation of the holes. Thus, the

holes can be in the form of small channels with central longitudinal axes that are angled relative to the central longitudinal axis of the flexible dispensing tube.

The apparatus of the present invention provides a laparoscopy instrument that comprises a first laparoscopy tube that can be placed surgically by a surgeon through an opening in the patient's abdominal wall, the first tube having a bore. An instrument body is provided that can be placed into the bore of the laparoscopy tube. The instrument body has proximal and distal end portions and an instrument body bore.

One or more flexible dispensing tubes are provided that each has a proximal and distal end. The tube is preferably sized and shaped to fit the instrument body bore and is flexible at least at the distal end portion thereof. In the preferred embodiment, each of the flexible dispensing tubes is in an elongated cylindrically shaped hollow tube of silicone, rubber, or rubber-like material. A nozzle is provided at the distal end of each of the dispensing tubes for dispensing liquids, gels and like medicinal materials into the patient's abdominal cavity.

Handles are provided on the instrument body for manipulating the distal end of the instrument body so that a contained flexible dispensing end portion of the dispensing tube can be moved in a sliding fashion. Further, a lever operates a pushrod to flex or pivot the distal end of the instrument body and the contained dispensing tube. This allows a wide range of positions for placement of the nozzle within the patient's abdominal cavity. The hollow bore of each of the dispensing tubes allows the transmission of fluid, gel, liquid, and like medicinal material between the proximal and distal end portions of the dispensing tube when the tube occupies the bore of the instrument body and the nozzle is positioned at a desired location within the patient's abdominal cavity.

In another embodiment, a syringe can be attached to a proximal opening of the instrument or to an extender tube. The syringe (or syringe and extender tube) enables the surgeon or an assistant to push gel, liquid, and like medicinal material through the bore of the instrument. By using the extender tube, the assistant can push the gel, liquid, etc. while the surgeon aims and positions the instrument for delivery of the surgical product.

BRIEF DESCRIPTION OF THE DRAWINGS:

For a further understanding of the nature and objects of the present invention, reference should be had to the following detailed description, taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals, and wherein:

FIGURE 1 is a side view of the preferred embodiment of the apparatus of the present invention;

FIGURE 2 is a side view of the preferred embodiment of the apparatus of the present invention illustrating the attachment of a sheet of surgical material thereto;

FIGURE 3 is a side view of the preferred embodiment of the apparatus of the present invention showing the sheet of surgical material in a furled condition about the distal end of the inserter instrument body;

5 FIGURE 4 is a side view of the preferred embodiment of the apparatus of the present invention showing the inserter instrument with a sheet of surgical material loaded in the distal end portion of the inserter instrument body;

10 FIGURE 5 is a schematic view illustrating placement of the apparatus of the present invention through a patient's abdominal wall and illustrating the method of the present invention;

FIGURE 6 is a side schematic view illustrating the method of the present invention;

FIGURE 7 is an exploded perspective view of the preferred embodiment of the apparatus of the present invention;

15 FIGURE 8 is a sectional view of the preferred embodiment of the apparatus of the present invention;

FIGURE 9 is a fragmentary, partially cut-away view of the preferred embodiment of the apparatus of the present invention;

FIGURE 10 is a top partial view of the preferred embodiment of the apparatus of the present invention;

20 FIGURE 11 is a top partial view of the preferred embodiment of the apparatus of the present invention illustrating an articulation of the distal end portion of the inserter instrument body;

FIGURE 12 is a fragmentary view of the lever portion of the preferred embodiment of the apparatus of the present invention;

25 FIGURE 13 is a fragmentary top view of the preferred embodiment of the apparatus of the present invention illustrating an articulation of the distal end portion of the inserter instrument;

FIGURE 14 is a partial, cut-away view of the distal end portion illustrating an alternative construction of the distal end portion of the inserter instrument;

30 FIGURE 15 is a fragmentary perspective view of the alternate construction of the distal end of the inserter instrument body;

FIGURE 16 is an exploded fragmentary view of the distal end portion of the inserter instrument body;

FIGURE 17 is a perspective exploded view of a second alternate embodiment of the apparatus of the present invention;

FIGURE 18 is a transverse cross-sectional view of the embodiment of Figure 17;

FIGURE 19 is a partial, sectional elevational view of the embodiment of Figures 17 and 5 18;

FIGURE 20 is a partial perspective view of the embodiment of Figures 17-19;

FIGURE 21 is a fragmentary sectional view of the third embodiment of the apparatus of the present invention illustrating the upper and lower jaws;

FIGURE 22 is a perspective view of a fourth embodiment of the apparatus of the present 10 invention;

FIGURE 23 is a perspective exploded view of a fifth embodiment of the apparatus of the present invention;

FIGURE 23A is a fragmentary section view of the fifth embodiment of Figure 23; and

FIGURES 24-25 are fragmentary sectional views of two of the head portions of the fourth 15 embodiment of the apparatus of the present invention;

FIGURE 26 is a perspective exploded view of a sixth embodiment of the apparatus of the present invention;

FIGURES 27A-27B are fragmentary perspective views of the present invention showing the articulating, telescoping dispensing end portion; and

FIGURE 28 is a fragmentary perspective view of the sixth embodiment of the apparatus 20 of the present invention showing a collection of dispensing tip portions of the apparatus.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT:

Figures 1-6 illustrate the preferred embodiment of the apparatus of the present invention 25 designated generally by the the numeral 10. Laparoscopy instrument 10 includes an elongated structure that can be placed through the abdominal wall 11 of a patient as shown in Figure 5. Also shown in Figures 5 and 6 is the patient's skin 12 and the abdominal cavity 13 into which an inserter instrument portion 24 of the instrument 10 will be placed.

Tubular port 14 extends through an opening 14A formed with the tubular member 14 through the patient's abdominal wall 11. This procedure of placing a port in the abdominal wall 30 11 is per se known. In such a procedure, it is known in the art to inflate the abdomen to give the surgeon a better view of the surgical site. The tubular port 14 is a commercially available structure that includes a proximal end 15 and a distal end 16. The tubular port 14 provides an elongated open end cylindrical bore 17 so that the surgeon can communicate between the

abdominal cavity 13 and the exterior of the patient. Cylindrical bore 17 is valved with valving member 18. The valving member 18 likewise provides a bore that is in communication with the cylindrical bore 17. Such a port 14 with its valving member 18 is sold commercially for use in laparoscopic surgery.

5 An elongated inserter tube member 20 is sized and shaped to fit the internal bore 17 of the tubular port 14. The tubular member 20 provides a generally cylindrical outer surface that is of an external diameter that is substantially the same as or slightly smaller than the internal diameter cylindrical bore 17. The bore 19 of valving member 18 is also generally cylindrically shaped to conform to the outer surface of tubular member 20. The inserter tube member 20 has
10 a proximal end 22 and a distal end 23. The tubular member 20 has a uniform cylindrical bore 21 that is open ended.

15 An elongated inserter instrument 24 is comprised of external tubular member 25 and internal tubular member 27 (see Figure 7). The external tubular member 25 has a handle 26 for manipulating it. Similarly, the internal tubular member 27 has a handle 28. The two handles 26,
28 are each in the form of a ring so that the surgeon can place one of his or her fingers through the handles 26, 28 for manipulating and sliding the member 27 relative to the member 25.

20 External tubular member 25 has a proximal end 29 and a distal end 30. A grasping portion 31 is attached to the distal end 30 as shown in Figures 7 and 9-13. Lever 32 is pivotally attached to the proximal 29 end portion of external tubular member 25. Lever 32 is attached to pushrod 34 so that pivoting of lever 32 about its pivot 33 operates to extend or retract the pushrod relative to external tubular member 25. The lever 32 is used to articulate grasping portion 31 into multiple angular positions relative to the central longitudinal axis of the external tubular member 25 as illustrated in Figures 10-11 and 13.

25 A cable 35 is attached to internal tubular member 27. The cable 35 extends through a longitudinal bore 36 within external tubular member 25. As will be described more fully hereinafter, the cable 35 is moved by pulling or pushing the internal tubular member 27 relative to the external tubular member 25 using handles 26, 28.

30 An articulating joint 37 forms a connection between external tubular member 25 and grasping portion 31. As shown in Figures 10-11 and 13, a pair of spaces 38, 39 are provided at articulating joint 37 for allowing the grasping portion 31 to move left to right and angulate relative to the central longitudinal axis of external tubular member 25 as shown in Figures 10-11 and 13. A pinned connection 40 is formed at articulating joint 37 between the distal end 30 of

external tubular member 25 and the grasping portion 31, allowing portion 31 to pivot upon tubular member 25.

Pushrod 34 includes an elbow section 41 that carries button 42. The button 42 fits in a recess 43. The recess 43 is formed on fixed member 44 of grasping portion 31. A moving member 45 is placed in close approximate to the fixed member 44. The moving member 45 travels away from the fixed member 44 when the cable 35 is pulled using lever 32. Cable 35 is attached at 46 to moving member 45. A coil spring 47 normally holds moving member 45 in face to face contact with fixed member 44. When the user pulls the internal tubular member 27 with handle 28, cable 35 pulls down underlying support 48 and moving member 45. A plurality of cable guides 49-51 are used to route the cable as shown in Figure 9 to the under side of moving member 45 as shown.

In Figure 9, arrow 52 illustrates the movement of pushrod 34 fore and aft depending upon the surgeon's manipulation of lever 32. In Figure 10, the pushrod 34 is a neutral position when the lever 32 is in an upright position, generally perpendicular to the central longitudinal axis of 15 external tubular member 25 as shown in Figure 7.

In Figure 11, the surgeon has pulled the pushrod 34 as shown by arrow 54. This causes the button 42 to travel to the rear portion of recess 43 thereby pivoting grasping portion 31 relative to external tubular member 25. In Figure 13, the surgeon has pushed the pushrod 34 using lever 32 as shown by the arrow 55. This causes the button 42 to travel to the forward portion of recess 43, thus pivoting the grasping portion 31 to the opposite angular position of that shown in Figure 11. In this fashion, the surgeon can articulate or pivot the grasping portion 31 relative to the central longitudinal axis of the external tubular member 25.

In Figure 9, arrow 53 designates a movement of moving member 45 away from fixed member 44. This is accomplished by pulling on the member 27 and its attached cable 35. Such a movement of member 45 in the direction of arrow 53 is used when either loading or releasing the sheet like member S to or from the instrument 10. The surgeon pulls the cable 35 to move member 45 away from member 44 producing a gap therebetween for application of an edge of sheet like member S thereto. In Figure 1, the gap has been formed between members 44 and 45 so that the surgeon can insert an edge of a sheet of material S into the gap formed between the 30 members 44 and 45.

- In Figure 2, the sheet of material S has been placed in the gap between the member 44 and 45. The surgeon then releases the member 27 so that the spring 47 pushes the member 45 into close face to face contact with the member 44. This action clamps a selected edge of the

sheet S between the members 44, 45 and allows the surgeon to furl the sheet S about grasping portion 31 as shown by the arrow 56 in Figure 3.

In Figure 4, arrow 57 indicates that the furled sheet S has been withdrawn into the bore of inserter tube 20. At this time, the sheet of material S has been furled about the grasping portion 31, and pulled into the bore 21. The combination of inserter tube 20, the sheet of material S, and the elongated inserter instrument 24 can now be inserted through tubular port member 14.

Figure 5, the surgeon uses port 14 to place the sheet of material S into the patient's abdominal cavity 13. This is accomplished by routing the distal end 23 of inserter tube 20 and the contained inserter instrument 24 through the bore 19 of valving member 18 and then through the bore 17 of tubular port member 14. The surgeon projects the inserter tube 20 into the abdominal cavity 13 until the distal end 23 is positioned close to the distal end 16 of tubular port member 14 as shown in Figure 5. The surgeon then holds the inserter tube 20, fixing its position relative to the tubular port 14. In the next step of the method, the surgeon forces the elongated inserter instrument 24 into the abdominal cavity by moving the elongated inserter instrument 24 relative to both inserter tube 20 and port 14 so that the grasping portion 31 and the furled sheet FS of material are exposed inside the abdominal cavity 13.

In Figure 5, the letters FS designate the furled sheet of material having been placed with the grasping portion 31 in the patient's abdominal cavity 13. The surgeon then rotates the elongated inserter instrument 24 as indicated by the arrow 58 in Figure 5. This rotation unfurls the sheet of material S to the position shown in Figure 6. A second port (such as member 14) can be used for placing a grasping instrument 59 into the abdominal cavity 13 for assisting the surgeon in application of the sheet of material S as illustrated in Figure 6.

An alternate construction of the grasping portion is shown in Figures 14-16, designated as grasping portion 31A. Grasping portion 31A includes a removable connection designated as 59 in Figure 14. Connections 62, 63 are formed between the instrument's receiving portions 31A and 45A and the ends 67, 69 of a pair of removable grasping portions 60, 61.

In Figure 15, a pre-packaged furled sheet FS of material is shown, furled about the removable ends 60, 61. The ends 60, 61 are pre-packaged with sheet S furled about these ends 61, 62. An edge of sheet FS is grasped between ends 61, 62. The furled sheet FS and ends 60, 61 would be contained within the bore 65 of an elongated disposable sleeve 64. The sleeve 64 provides a pull tab 66 so that the user can install the furled sheet FS avoiding premature unfurling by simply holding and manipulating the sleeve 64 at tab 66. After the removable ends

60, 61 are installed by perfecting a connection at the joints 62, 63 and backloading the furled sheet FS into sleeve 20, the surgeon then pulls on the pull tab 66 to remove the sleeve 64 so that the surgery can proceed.

In Figure 16, removable end 60, provides a projection 67 that mates with a correspondingly shaped socket 31B of grasping portion 31A. Similarly, the moving member 45A provides a socket 45B that forms a connection with projecting portion 69 of end 61. The end members 60, 61 each provide correspondingly sized and shaped flat surfaces 60A, 61A that abut in face to face relation when the coil spring 47 forces members 60, 61 together.

The connection between projections 67, 69 and sockets 31B and 45B can be a wedge lock or taper lock type connection to ensure a tight fit. In the embodiment of Figures 14-16, the removable ends 61, 62 and the furled sheet FS and sleeve 64 could be in a presterilized blister pack for example.

Figures 17-20 show a second alternate embodiment of the apparatus of the present invention designated generally by the numeral 70. Instrument 70 includes an external tubular member 25 that is constructed in accordance with the preferred embodiment of Figures 1-13. The internal member 27 is constructed generally in accordance with the preferred embodiment. However, the internal tubular member 27 carries a pushrod 71 instead of cable 35.

Pushrod 71 has a distal end in the form of a spherical member or ball 72. The member 25 has a proximal end 29 and a central longitudinal bore that accepts the internal tubular member 27. This allows the member 27 to slide within the bore of the member 25. Handle 26 and 28 enable a surgeon to grip and manipulate instrument 70 and to slide member 27 relative to member 25.

As with the preferred embodiment, the embodiment of Figure 17-20 includes an external tubular member 25 having a hollow bore that accepts pushrod 34. The pushrod 34 is attached to lever 32. The lever 32 affixes at pivot 33 to external tubular member 25.

In the embodiment of Figures 17-20, a pivotal connection 73 is formed between the member 25 and grasping portion 74. Lever 32 can be pivoted about its pivot 33 in order to extend or retract pushrod 34. As with the preferred embodiment, the pushrod 34 has an elbow section 41 and a button portion 42. As with the preferred embodiment, the button 42 occupies recess 43.

The pushrod 34 and its button 42 can be used to articulate grasping portion 74 about pivot 73 relative to external tubular member 25. This pivoting action of grasping portion 74 relative

to member 25 operates the same as the pivoting that was shown and described in Figures 10-13 in the description of the preferred embodiment.

In Figure 19, pushrod 71 is shown having a distal end with ball 72 that fits socket 79. The socket 79 is partially cone shaped, also having a hemispherical portion 89 that registers against ball 72. Lower jaw 76 is in a closed position when ball 72 moves forward and engages the hemispherical portion 89 of socket 79. This pushes the lower jaw 76 into engagement with the upper jaw 75.

The jaw 76 has an inclined surface 90 that is engaged by the ball 72 as the pushrod 71 moves forward. Jaw 76 has a flat surface 83 that engages shoulder 82 of undersupport 80. The undersupport 80 has a flat surface 81 that receives the enlarged proximal section 91 of lower jaw 76.

In order to open the jaws 75, 76 the user pulls handle 28 of member 27. This also places pushrod 71 in tension, pulling the ball 72 away from the hemispherical portion 89 of socket 79. As ball 72 is withdrawn (see arrow 85 in Figure 19), lower jaw 76 drops in the direction of arrow 79 due to its own weight. Shoulder 82 engages the flat surface 83 of enlarged portion 91, holding the jaw 76 in its operative position adjacent jaw 75. There is enough of a gap 84 in between the enlarged portion 91 and the undersupport 80 so that the lower jaw 76 moves away from the upper jaw 75 forming a gap therebetween to hold sheet S.

The external member 25 and jaws 75, 76 fit within the bore 21 of inserter tube 20. The member 25 is longer than tube 20 so that jaws 75, 76 can be placed inside the patient's abdominal cavity while the surgeon is holding handles 26, 28 and manipulating lever 32. This allows jaws 26, 28 to be opened and closed inside the patient's abdominal cavity. This allows the jaws 75, 76 to articulate about pivot 73. The jaws 75, 76 can be opened and closed, even when the jaws are articulated to the left or to the right of the central longitudinal axis of member 25.

As with the preferred embodiment, a sheet S of surgical material can be gripped by jaws 75, 76 and then furled about the jaws 75, 76 for entry into inserter tube 20. The jaws 75, 76 preferably present a generally cylindrically shaped outer surface when the jaws 75, 76 are closed. The inner surface of the jaws 75, 76 could be smooth for delicate materials which might break with a serrated gripper, and serrated for slipperier materials which would not break with a gripper having serrations. Serrations of various coarseness could be used (the slipperier and more tough the material to be gripped, the larger the serrations).

In Figure 21, a fourth embodiment of the apparatus of the present invention is shown, designated as 92 and illustrating an alternate jaw and surgical sheet arrangement and pre-

packaging. To package the surgical material S with the disposable jaws 75, 76 rolling (as shown in Figure 15) of the material S is usually easier and probably cheaper. However, rolling will generally not work well when the material S has a "memory" which might hinder unrolling during surgery; then it is preferably packaged flat in the interior 94 of envelope 93 (see Figure 22). Plastic clip 95 shown in Figure 22 is resilient and provides a recess 96 that conforms to the shape of the outer surface of the assembled upper jaw 75 and lower jaw 76. Plastic clip 95 holds jaws 75 and 76 together and secures the surgical sheet S in place. Plastic clip 95 pulls off after the jaws 75, 76 are snapped onto instrument in surgery as with the embodiment of Figures 14-16.

Figures 23-25 show a fifth embodiment of the apparatus of the present invention designated generally by the numeral 100. In Figures 23-26, a laparoscopic instrument 100 can be used to transmit gels, liquids, and like medicines to selected portions of the patient's abdominal cavity using a variety of dispensing head portions as will be discussed more fully hereinafter.

Laparoscopic instrument 100 includes an elongated main body 101 having a pushrod 102 that extends between collar 107 and control lever 103. The instrument body 101 has a proximal end 104, a distal end 105, and a pivotal connection 106 is provided between main body 101 and collar 107.

As shown in Figure 23A, collar 107 has a hollow open ended bore 110 that communicates with a similar elongated open ended cylindrical bore 111 of main body 101. The bore sections 110, 111 are sized and shaped to receive elongated cylindrically shaped dispensing member 112 in a removable fashion. The user can select a particular elongated dispensing member 112 having a selected member head portion 115-122 as shown in Figure 23.

Dispensing member 112 is an elongated flexible conduit member such as a flexible hose. The dispensing member 112 has a proximal end 113, a distal end 114, and an open ended bore 112A that extends the full length of the dispensing member 112 so that fluids can be conveyed from the proximal 113 to the distal 114 end of dispensing member 112 and through a selected head 115-122 into the patient's abdomen.

Inner shaft 123 provides proximal end 124, distal end 125, and open ended bore 126. Inner shaft 123 is equipped with a rubber gasket seal 127 at its proximal end portion. During use, inner shaft 123 is first placed inside the bore 11 of main body 101. The surgeon then selects a desired elongated flexible dispensing member 112 having a particular desired head 115-122 as selected by the surgeon.

5 The elongated flexible dispensing member 112 is placed inside the bore 110, 111 sections of collar 107 and main body 101. Further, inner shaft 123 is placed into instrument main body 101, bore 111 at the proximal 104 end of main body 101. Thus, in the proximal 104 region of instrument main body 101, dispensing tube 112 fits the bore 126 of inner shaft 123. The combination of dispensing member 112 and inner shaft 123 fits inside bore 111. Handles 128, 129 allow the surgeon to grip and manipulate main body 101, inner shaft 123, and the particular selected long flexible dispensing member 112.

10 With the present invention, a variety of flexible plastic dispensing tube members 112 can be provided. As shown in Figure 23, these various heads 115-122 have different designs which allow different types of liquid, gels, medicinal materials to be administered in different patterns of application. These different heads 115-122 can be used, for example to provide a pin point, broad, shower-like or other type of spray within the patient's abdomen. These tube like dispensing members 112 preferably consist of a long flexible tube member which inserts into the main body 101 through its bore 110,111.

15 The chosen or selected flexible plastic dispensing tube member 112 also passes through the bore 126 of inner shaft 123 which slides into main body 101, bore 111. The flexible dispensing tube 112 thus traverses the entire length of the main body 101 as well as the inner shaft 123. The handle 129 portion of inner shaft 123 will be closely positioned to the proximal 104 end of main body 101 and in close proximity to the handle 128 of main body 101.

20 The distal end 114 of the particular elongated flexible dispensing member 112 exits the bore 111 of main body 101 as shown in Figure 23 wherein head 115 extends beyond the distal end of collar 107. The proximal end 113 of dispensing tube member 112 slides through a firm rubber gasket seal 127 that grips the dispensing tube member 112 at its proximal end 113 and holds it.

25 Gasket seal 127 also fits over the proximal 124 end of inner shaft 123 as shown in Figure 23. The rubber gasket seal 127 forms a seal between the proximal end 124 of inner shaft 123 and the proximal end 113 of tube 112. The handles 128, 129 allow the surgeon to slide the inner shaft 123 and with it the selected flexible plastic dispensing tube member 112 back and forth (see arrow 130, Figure 23) to reach greater or lesser depth and/or hard to reach areas within the 30 patient's abdomen during surgery.

The collar 107 provides an articulating end portion to instrument 100 that can be moved left or right as indicated by arrows 108, 109 in Figure 23. The articulating collar 107 can be moved left or right (or in any direction when the entire instrument 100 is turned or rotated) by

moving control lever 103 to move pushrod 102. As shown in Figure 23, the entire mechanism of lever 103, pushrod 102, pivot 106 is the same operating mechanism as the mechanism shown in Figures 9-13 in the preferred embodiment for pivoting the jaws relative to the instrument body in that embodiment.

5 The present invention thus allows additional maneuvering ability for positioning the head 115-122 as selected by the surgeon for application of a desired liquid gel or medicinal material and with a desired spray, pin point, broad shower or the like depending upon the head selected. Any chosen material, gel, liquid, medicine to be administered to the patient is applied by attaching a standard syringe to the proximal end 113 of dispensing tube 112 and dispensing the 10 contents of the syringe into the bore of the dispensing tube member 112.

15 Figures 24 and 25 show in cross section examples of the spray patterns to be obtained by using head 119 and 121 respectively. These head portions 119, 121 have an outwardly angled plurality of holes 130 and 131 to direct liquids, gels and like medicinal material as far outward as possible for the widest dispersion. The head 119 would preferably be used with liquids. The head 121 would preferably be used with gels.

20 Figure 26 is a perspective exploded view of a sixth embodiment of the apparatus of the present invention, designated generally by the numeral 133. Laparoscopy instrument 133 includes an elongated instrument main body 101 having a central longitudinal open ended hollow bore 111 that is sized and shaped to receive one of a plurality of flexible dispensing tubes 112. Body 101 has a proximal end 104 and a distal end 105. In the embodiment of Figure 26, the handles 128, 129 of Figure 23 have been removed.

25 As shown in Figure 26, each dispensing tube 112 provides a proximal end portion 113 and the distal end portion 114. The distal end 114 can be provided any one of a number of different head configurations such as the head configurations 115-122 shown in Figure 28.

30 As with the embodiment of Figures 22-23A, a lever 103 is pivotally attached to the outer surface of body 101. The lever 103 operates pushrod 102 to articulate annular collar 107 relative to main body 101. A pivot 106 joins annular collar 107 to main body 101. Arrows 108, 109 in Figure 26 illustrate the articulation of annular collar 107 relative to the main body 101 and its central longitudinal axis. In Figure 26, the bore 112A of dispensing tube 112 is designed to receive the male end portion 135 of syringe 134 as shown by arrow 136 in Figure 26. This allows a standard syringe 134 to attached to the proximal end 113 of dispensing tube 112.

An extender tube 137 can also be used to form an attachment between the proximal 113 end of dispensing tube 112A and a syringe 134. The extender tube 137 provides a proximal end

140 and a distal end 135. Extender tube 137 also provides a longitudinally extended open ended bore 138. An attachment can be made between syringe 134 and more particularly its distal 135 end and the proximal end 140 of extender tube 137 as shown by arrow 141 in Figure 26.

Once the syringe 134 is attached to the proximal 113 end of dispensing tube 112 or to extender tube 137 at its proximal end 140, a surgical assistant can push a gel, liquid, medicine, etc. through the bore 138 of extender tube 137 and/or through the bore 112A of flexible dispensing tube 112 to one of the selected heads 115-121. Simultaneously, the surgeon aims and positions the selected head 115-121 and the entire instrument 133 for delivery of the selected surgical product to the surgical site selected within the patient's body cavity.

In Figure 26, arrows 142 illustrate the assembly of dispensing tube 112 into the bore 110 of collar 107 and into the bore 111 of main body 101. Once in position within the bore 111 of main body 101, dispensing tube 112 can be moved longitudinally in a sliding fashion as shown by arrow 132 in Figure 27A.

In Figure 28, a plurality of dispensing heads are shown, designated generally by the numerals 115-121. Other configurations for the head 115-121 can be seen in prior copending patent application serial no. 08/644,504 incorporated herein by reference.

In Figure 27B, an additional head 143 is shown that is spherical in shape. Otherwise, the head 143 is simply on continuation and is mounted on the distal end 114 or dispensing tube 112. The head 143 is spherical in shape, providing dispensing openings 144 over the entire surface of spherical portion as shown in Figure 27B.

The following table lists the parts numbers and parts descriptions as used herein and in the drawings attached hereto.

PARTS LIST

| | <u>Part Number</u> | <u>Description</u> |
|----|--------------------|------------------------|
| 25 | 10 | laparoscopy instrument |
| | 11 | abdominal wall |
| | 12 | skin |
| | 13 | abdominal cavity |
| | 14 | tubular port |
| | 15 | proximal end |
| | 16 | distal end |
| | 17 | cylindrical bore |
| | 18 | valving member |

| | | |
|----|-----|-------------------------|
| | 19 | bore |
| | 20 | inserter tube |
| | 21 | cylindrical bore |
| | 22 | proximal end |
| 5 | 23 | distal end |
| | 24 | inserter instrument |
| | 25 | external tubular member |
| | 26 | handle |
| | 27 | internal tubular member |
| 10 | 28 | handle |
| | 29 | proximal end |
| | 30 | distal end |
| | 31 | grasping portion |
| | 31A | grasping portion |
| 15 | 31B | socket |
| | 32 | lever |
| | 33 | pivot |
| | 34 | pushrod |
| | 35 | cable |
| 20 | 36 | longitudinal bore |
| | 37 | articulating joint |
| | 38 | space |
| | 39 | space |
| | 40 | pinned connection |
| 25 | 41 | elbow section |
| | 42 | button |
| | 43 | recess |
| | 44 | fixed member |
| | 45 | moving member |
| 30 | 45A | grasping portion |
| | 45B | socket |
| | 46 | attachment |
| | 47 | coil spring |

| | | |
|----|-----|----------------------|
| | 48 | underlying support |
| | 49 | cable guide |
| | 50 | cable guide |
| | 51 | cable guide |
| 5 | 52 | arrow |
| | 53 | arrow |
| | 54 | arrow |
| | 55 | arrow |
| | 56 | arrow |
| 10 | 57 | arrow |
| | 58 | arrow |
| | 59 | removable connection |
| | 60 | removable end |
| | 61 | removable end |
| 15 | 62 | removable connection |
| | 63 | removable connection |
| | 63A | joint |
| | 63B | joint |
| | 64 | sleeve |
| 20 | 65 | cylindrical bore |
| | 66 | pull tab |
| | 67 | projection |
| | 69 | projection |
| | 70 | instrument |
| 25 | 71 | cable |
| | 72 | ball |
| | 73 | pivot |
| | 74 | grasping portion |
| | 75 | upper jaw |
| 30 | 76 | lower jaw |
| | 77 | flat surface |
| | 78 | flat surface |
| | 79 | socket |

| | | |
|----|------|--------------------------|
| | 80 | undersupport |
| | 81 | flat surface |
| | 82 | shoulder |
| | 83 | flat surface |
| 5 | 84 | gap |
| | 85 | arrow |
| | 86 | arrow |
| | 87 | groove |
| | 88 | keyway |
| 10 | 89 | hemispherical |
| | 90 | inclined surface |
| | 91 | enlarged portion |
| | 92 | jaw assembly |
| | 93 | envelope |
| 15 | 94 | interior |
| | 95 | plastic clip |
| | 100 | laparoscopy instrument |
| | 101 | body |
| | 102 | pushrod |
| 20 | 103 | lever |
| | 104 | proximal end |
| | 105 | distal end |
| | 106 | pivotal connection |
| | 107 | annular collar |
| 25 | 108 | arrow |
| | 109 | arrow |
| | 110 | bore |
| | 111 | bore |
| | 112 | flexible dispensing tube |
| 30 | 112A | bore |
| | 113 | proximal end |
| | 114 | distal end |
| | 115 | head |

| | | |
|----|-----|---------------------------|
| | 116 | head |
| | 117 | head |
| | 118 | head |
| | 119 | head |
| 5 | 120 | head |
| | 121 | head |
| | 122 | head |
| | 123 | inner shaft |
| | 124 | proximal end |
| 10 | 125 | distal end |
| | 126 | bore |
| | 127 | rubber gasket seal |
| | 128 | handle |
| | 129 | handle |
| 15 | 130 | holes |
| | 131 | holes |
| | 132 | arrow |
| | 133 | laparoscopy instrument |
| | 134 | syringe |
| 20 | 135 | narrowed dispensing end |
| | 136 | arrow |
| | 137 | extender tube |
| | 138 | tube bore |
| | 139 | end portion |
| 25 | 140 | end portion |
| | 141 | arrow |
| | 142 | arrow |
| | 143 | spherical dispensing head |
| | 144 | openings |
| 30 | S | sheet |
| | FS | furled sheet |

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the

embodiments herein detailed in accordance with the descriptive requirement of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting sense.

What is claimed as invention is:

CLAIMS

1. A method of dispensing a liquid medicinal material into a patient's body cavity, comprising the steps of:

5 a) surgically forming a port through the patient's body cavity wall;

b) said placement of said port including placing a first tubular member, having proximal and distal end portions and an elongated bore into the patient's body cavity, said proximal end having a valving member that valves the flow of gases through the bore and between the proximal and distal ends;

10 c) inserting a second tubular member into the bore of the first tubular member, and through the valve the second tubular member being an instrument body with a moving distal end portion that can be manipulated by the surgeon;

d) valving the flow of gases between the patient's body cavity and the proximal end of the first tubular member with the valving member;

15 e) extending the distal end of the second tubular member into the patient's body cavity;

f) placing a flexible dispensing tube into the bore of the second tubular member, the second tubular member having a distal end with a nozzle for applying the liquid with a desired spray pattern;

20 g) attaching a syringe to the proximal end of the dispensing tube;

h) transmitting the liquid from the syringe into the patient's body cavity via the nozzle; and

i) articulating the instrument body distal end to flex the distal end of the dispensing tube.

25 2. The method of claim 1 wherein the second tubular body is generally cylindrically shaped, and includes said moving distal end portion, the entire length of said second tubular body having an open ended bore and further comprising the step of pivoting the distal end portion in order to flex the dispensing tube.

30 3. The method of claim 1 wherein the second tubular member is a flexible tube at least at the distal end portion thereof.

4. The method of claim 1 wherein there are a plurality of dispensing tubes, each having a nozzle end portion with a nozzle spray pattern, and in step "f" the surgeon selects a delivery tube from the plurality of dispensing tubes with the desired nozzle spray pattern.

5. The method of claim 1 wherein the second tubular member has a pivot at the distal end portion thereof, and in step "h", the distal end of the second tubular member is pivoted during articulating of the instrument body and the dispensing tube.

6. The method of claim 1 wherein the second tubular member has a nozzle with a 5 plurality of openings therethrough.

7. The method of claim 1 wherein each dispensing tube is longer than the instrument body and further comprising the step of sliding the dispensing tube relative to the instrument body during a positioning of the nozzle relative to a desired location within the patient's body cavity.

10 8. The method of claim 1 wherein the instrument body has an actuator at its proximal end for manipulating the distal end thereof and further comprising the step of moving the distal end of the dispensing tube by manipulating the actuator.

9. The method of claim 8 wherein the actuator is operable by the surgeon when the nozzle is inside the patient's body cavity.

15 10. A surgical instrument comprising:

a) a tube that can be surgically placed by a surgeon through a surgical opening in a patient's body cavity wall, said tube having a bore.

b) an instrument body that can be placed in the bore of the tube, and having proximal and distal end portions and an instrument body bore;

20 c) a flexible dispensing tube that has proximal and distal end portions, the tube being sized and shaped to fit the instrument body bore and flexible at least at the distal end portion thereof;

d) a nozzle at the distal end of the dispensing tube for dispensing liquids, gels, and like medicinal materials into a patient's body cavity;

25 e) the distal end of the instrument body being movable into multiple positions so that the contained flexible distal end portion of the dispensing tube also moves therewith;

f) a syringe for transmitting fluid between the proximal and distal end portions of the dispensing tube when the tube occupies the bore of the instrument body and the nozzle is positioned within the patient's body cavity.

30 11. The surgical endoscopic instrument of claim 10 further comprising a flexible extension tube that is positioned in between the syringe and the proximal end of the dispensing tube, enabling a surgical assistant to dispense a gel, liquid, medicine or the like from the syringe

into the extension tube and dispensing tube while the surgeon arms and positions the distal end of the dispensing tube.

12. The surgical endoscopic instrument of claim 10 wherein the instrument body has a pivot and the distal end portion of the instrument body pivots relative to the proximal end of the instrument body.

13. The surgical endoscopic instrument of claim 12 wherein the instrument body has an open ended bore that extends from the proximal end, through the pivot to the distal end.

14. The surgical endoscopic instrument of claim 10 wherein the dispensing tube is slidably mounted within the instrument body bore.

10 15. The surgical endoscopic instrument of claim 10 wherein the instrument body comprises a pair of body sections including a smaller distal section and a larger proximal section.

16. The surgical endoscopic instrument of claim 15 wherein each of the sections has a bore.

15 17. The surgical endoscopic instrument of claim 10 wherein the nozzle has a plurality of openings.

18. The surgical endoscopic instrument of claim 17 wherein the nozzle has an array of openings.

19. The surgical endoscopic instrument of claim 10 wherein there are a plurality of flexible dispensing tubes, each being sized and shaped to fit the instrument body bore, each having a nozzle with a selected spray pattern so that a surgeon can select a desired spray pattern by selecting a particular dispensing tube and inserting said selected tube into the instrument body bore.

20 25 20. The surgical endoscopic instrument of claim 10 wherein the instrument body is generally cylindrically shaped.

21. The surgical endoscopic instrument of claim 10 wherein the dispensing tube is of a flexible rubber-like material.

22. A method of dispensing a liquid medicinal material into the patient's body cavity, comprising the steps of:

30 a) surgically forming a port through the patient's body cavity wall;
b) said placement of said port including placing a first tubular member, having proximal and distal end portions and an elongated bore into the patient's body cavity;

10 c) inserting a second tubular member into the bore of the first tubular member, the second tubular member being an instrument body with a moving distal end portion that can be manipulated by the surgeon;

5 d) extending the distal end of the second tubular member into the patient's body cavity;

e) placing a flexible dispensing tube into the bore of the second tubular member, the second tubular member having a distal end with a nozzle for applying the liquid with a desired spray pattern;

f) attaching a syringe to the proximal end of the dispensing tube;

10 g) transmitting the liquid from the syringe into the patient's body cavity via the nozzle; and

h) articulating the instrument body distal end to flex the distal end of the dispensing tube.

15 23. The method of claim 22 wherein the second tubular body is generally cylindrically shaped, and includes said moving distal end portion, the entire length of said second tubular body having an open ended bore and further comprising the step of pivoting the distal end portion in order to flex the dispensing tube.

24. The method of claim 22 wherein the second tubular member is a flexible tube at least at the distal end portion thereof.

20 25. The method of claim 22 wherein there are a plurality of dispensing tubes, each having a nozzle end portion with a nozzle spray pattern, and in step "f" the surgeon selects a delivery tube from the plurality of dispensing tubes with the desired nozzle spray pattern.

25 26. The method of claim 22 wherein the second tubular member has a pivot at the distal end portion thereof, and in step "h", the distal end of the second tubular member is pivoted during articulating of the instrument body and the dispensing tube.

27. The method of claim 22 wherein the second tubular member has a nozzle with a plurality of openings therethrough.

30 28. The method of claim 22 wherein each dispensing tube is longer than the instrument body and further comprising the step of sliding the dispensing tube relative to the instrument body during a positioning of the nozzle relative to a desired location within the patient's body cavity.

29. The method of claim 22 wherein the instrument body has an actuator at its proximal end for manipulating the distal end thereof and further comprising the step of moving the distal end of the dispensing tube by manipulating the actuator.

30. The method of claim 29 wherein the actuator is operable by the surgeon when the 5 nozzle is inside the patient's body cavity.

31. A method of dispensing a liquid medicinal material into the patient's body cavity, comprising the steps of:

a) surgically forming a port through the patient's body cavity wall;

b) said placement of said port including placing a first tubular member, 10 having proximal and distal end portions and an elongated bore into the patient's body cavity, said proximal end having a valving member that valves the flow of gases through the bore and between the proximal and distal ends;

c) inserting a second tubular member into the bore of the first tubular member, and through the valve, the second tubular member being an instrument body with a 15 moving distal end portion that can be manipulated by the surgeon;

d) valving the flow of gases between the patient's body cavity and the proximal end of the first tubular member with the valving member;

e) placing a dispensing tube into the bore of the second tubular member, the second tubular member having a flexible distal end portion with a nozzle for applying the liquid 20 with a desired spray pattern;

f) extending the distal end of the second tubular member into the patient's body cavity;

g) transmitting the liquid into the patient's body cavity via the nozzle; and

h) articulating the instrument body distal end to flex the distal end of the 25 dispensing tube.

32. The method of claim 31 wherein the second tubular body is generally cylindrically shaped, and includes said moving distal end portion, the entire length of said second tubular body having an open ended bore and further comprising the step of pivoting the distal end portion in order to flex the dispensing tube.

33. The method of claim 31 wherein the second tubular member is a flexible tube at 30 least at the distal end portion thereof.

34. The method of claim 31 wherein there are a plurality of dispensing tubes, each having a nozzle end portion with a nozzle spray pattern, and in step "f" the surgeon selects a delivery tube from the plurality of dispensing tubes with the desired nozzle spray pattern.

5 35. The method of claim 31 wherein the second tubular member has a pivot at the distal end portion thereof, and in step "h", the distal end of the second tubular member is pivoted during articulating of the instrument body and the dispensing tube.

36. The method of claim 31 wherein the second tubular member has a nozzle with a plurality of openings therethrough.

10 37. The method of claim 31 wherein each dispensing tube is longer than the instrument body and further comprising the step of sliding the dispensing tube relative to the instrument body during a positioning of the nozzle relative to a desired location within the patient's abdominal cavity.

15 38. The method of claim 31 wherein the instrument body has an actuator at its proximal end for manipulating the distal end thereof and further comprising the step of moving the distal end of the dispensing tube by manipulating the actuator.

39. The method of claim 38 wherein the actuator is operable by the surgeon when the nozzle is inside the patient's body cavity.

40. A surgical endoscopic instrument for dispensing fluids through a surgically formed port in a patient's body cavity wall comprising;

20 a) a tube that can be surgically placed by a surgeon through a surgical opening in a patient's body cavity wall, said tube having a bore.

b) an instrument body that can be placed in the bore of the tube, and having proximal and distal end portions and an instrument body bore;

25 c) a dispensing tube that has proximal and distal end portions, the tube being sized and shaped to fit the instrument body bore and being flexible at least at the distal end portion thereof;

d) a nozzle at the distal end of the dispensing tube for dispensing liquids, gels, and like medicinal materials into a patient's body cavity;

30 e) the distal end of the instrument body being movable into multiple positions so that the contained flexible distal end portion of the dispensing tube also moves therewith;

f) a dispensing tube bore for transmitting fluid between the proximal and distal end portions of the dispensing tube when the tube occupies the bore of the instrument body and the nozzle is positioned within the patient's body cavity.

41. The surgical endoscopic instrument of claim 40 wherein the instrument body has a pivot and the distal end portion of the instrument body pivots relative to the proximal end of the instrument body.

42. The surgical endoscopic instrument of claim 41 wherein the instrument body has an open ended bore that extends from the proximal end, through the pivot to the distal end.

43. The surgical endoscopic instrument of claim 40 wherein the dispensing tube is slidably mounted within the instrument body bore.

44. The surgical endoscopic instrument of claim 40 wherein the instrument body comprises a pair of body sections including a smaller distal section and a larger proximal section.

45. The surgical endoscopic instrument of claim 44 wherein each of the sections has a bore.

46. The surgical endoscopic instrument of claim 40 wherein the nozzle has a plurality of openings.

47. The surgical endoscopic instrument of claim 46 wherein the nozzle has an array of openings.

48. The surgical endoscopic instrument of claim 40 wherein there are a plurality of flexible dispensing tubes, each being sized and shaped to fit the instrument body bore, each having a nozzle with a selected spray pattern so that a surgeon can select a desired spray pattern by selecting a particular dispensing tube and inserting said selected tube into the instrument body bore.

49. The surgical endoscopic instrument of claim 40 wherein the instrument body is generally cylindrically shaped.

50. The surgical endoscopic instrument of claim 40 wherein the dispensing tube is of a flexible rubber-like material.

51. A laparoscopy instrument for inserting a surgical sheet like article into a patient's abdomen comprising:

a) an instrument body that includes a first member having a bore, a proximal end portion and a distal end portion;

b) a second member that slides in the bore of the first member between first and second positions;

c) a set of jaws positioned at the distal end of the first member, said jaws being active jaws, operable between open and closed positions, the jaws being extended longitudinally, each jaw having a gripping surface that abuts the other in the closed position, the jaws being of a length to support the sheet article along a substantial portion of one of its sides;

5 d) a tubular cannula through which the instrument body can be inserted during a surgical laparoscopic procedure so that the distal end of the instrument body and the jaws can communicate with the patient's abdominal cavity when the instrument body is inserted through the cannula;

10 e) the second member defining an operator with a handle that can be manipulated by a surgeon, the handle positioned at the proximal end of the instrument body for opening and closing the jaws.

52. The surgical instrument of claim 51 wherein the jaws are movably connected to the instrument body so that the jaws can articulate with respect to the instrument body.

15 53. The surgical instrument of claim 51 wherein the jaws are pivotally connected to the instrument body so that the jaws can pivot with respect to the instrument body.

54. The surgical instrument of claim 51 wherein the jaws are movably connected to the instrument body so that the jaws can articulate with respect to the instrument body, and a lever mounted on the proximal end of the instrument body enables the surgeon to manipulate the jaws into multiple positions.

20 55. The surgical instrument of claim 54 wherein the jaws are pivotally connected to the instrument body so that the jaws can pivot with respect to the instrument body, and further comprising a lever that is operable by the surgeon to move the jaws into multiple positions as the jaws pivot relative to the instrument body.

25 56. The surgical instrument of claim 51 wherein the instrument body is an elongated linear member that has a central longitudinal axis.

57. The surgical instrument of claim 51 wherein the jaws pivot about a pivotal axis that is generally perpendicular to the central longitudinal axis.

58. The surgical instrument of claim 51 wherein the jaws each have flat surfaces that abut to grip the sheet therebetween.

30 59. The surgical instrument of claim 51 further comprising a pushrod having a distal end that engages one of the jaws, the pushrod being operable to open and close the one jaw relative to the other jaw.

60. The surgical instrument of claim 51 further comprising a ball that fits the distal end of the pushrod and a socket on the jaw for receiving the ball.

61. The surgical instrument of claim 51 further comprising a pushrod that extends through the first member to engage the jaws, movement of the pushrod effecting a pivotal movement of the jaws when the jaws are in an open or in a closed position.

5 62. A laparoscopy instrument for inserting a surgical sheet like article into a patient's abdomen comprising:

10 a) an elongated instrument body that includes an elongated tubular member having a longitudinal bore, a proximal end portion and a distal end portion;

b) an elongated operator member that slides in the bore of the first member between first and second positions;

15 c) a set of jaws positioned at the distal end of the tubular member, said jaws being active jaws, operable between open and closed positions, the jaws being extended longitudinally, each jaw having a gripping surface that abuts the other in the closed position, the jaws being of a length to support the sheet article along a substantial portion of one of its sides;

d) a tubular cannula having a cannula bore through which the instrument body can be inserted during a surgical laparoscopic procedure, the instrument body being longer than the cannula bore so that the distal end of the instrument body and the jaws can communicate with the patient's abdominal cavity when the instrument body is inserted through the cannula;

20 and

e) the operator member having a handle that can be manipulated by a surgeon, the handle positioned at the proximal end of the instrument body for enabling a surgeon to move the operator for opening and closing the jaws.

63. The laparoscopy instrument of claim 62 further comprising a handle at the 25 proximal end for manipulating the instrument body.

64. The laparoscopy instrument of claim 62 wherein the jaws are between about two and five (2 - 5) inches in length.

65. The laparoscopy instrument of claim 62 wherein the second member includes a 30 pushrod that extends to the jaws.

66. The laparoscopy instrument of claim 62 wherein the second member includes a pushrod with an attachment that extends to and from a connection with a first one of the jaws, the other jaw being fixed relative to the first jaw.

67. The laparoscopy instrument of claim 62 further comprising a pivot at the distal end of the instrument body, said pivot enabling the jaws to articulate about an articulation axis.

68. The laparoscopy instrument of claim 63 wherein the jaws open and close in a plane and the jaw articulation axis lies in said plane.

5 69. The laparoscopy instrument of claim 63 wherein the outer surfaces of the jaws define a generally cylindrical shape.

70. A laparoscopy instrument for inserting a surgical sheet like article into a patient's abdomen comprising:

a) an instrument body with a proximal end portion and a distal end portion;

10 b) a set of jaws positioned at the distal end of the first member, said jaws being active jaws, operable between open and closed positions, the jaws being extended longitudinally, each jaw having a gripping surface that abuts the other in the closed position, the jaws being of a length of at least three to four (3-4) inches to support the sheet article along a substantial portion of one of its sides;

15 c) a tubular cannula with a bore through which the instrument body and jaws can be inserted during a surgical laparoscopic procedure so that the distal end of the instrument body and the jaws can communicate with the patient's abdominal cavity when the instrument body is inserted through the cannula bore;

20 d) an operator with a handle that can be manipulated by a surgeon, the handle positioned at the proximal end of the instrument body for opening and closing the jaws; and

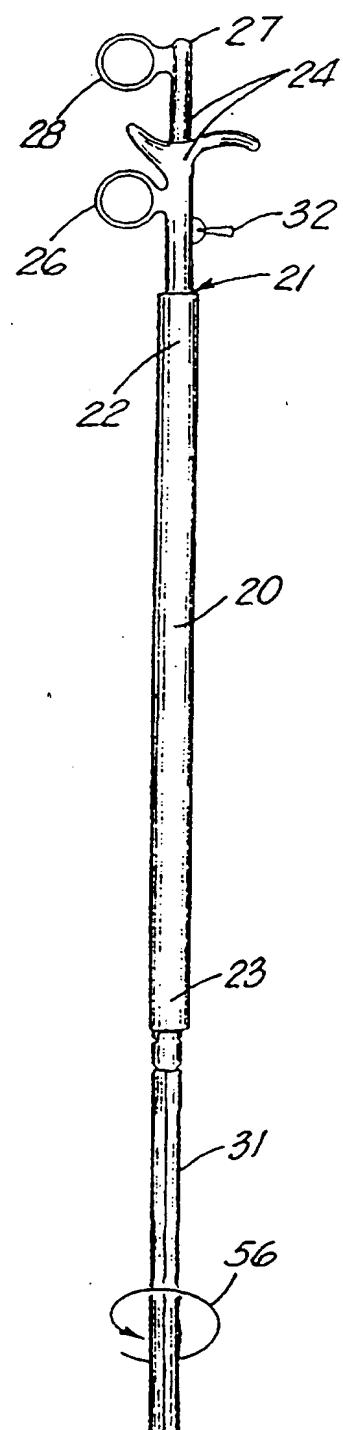
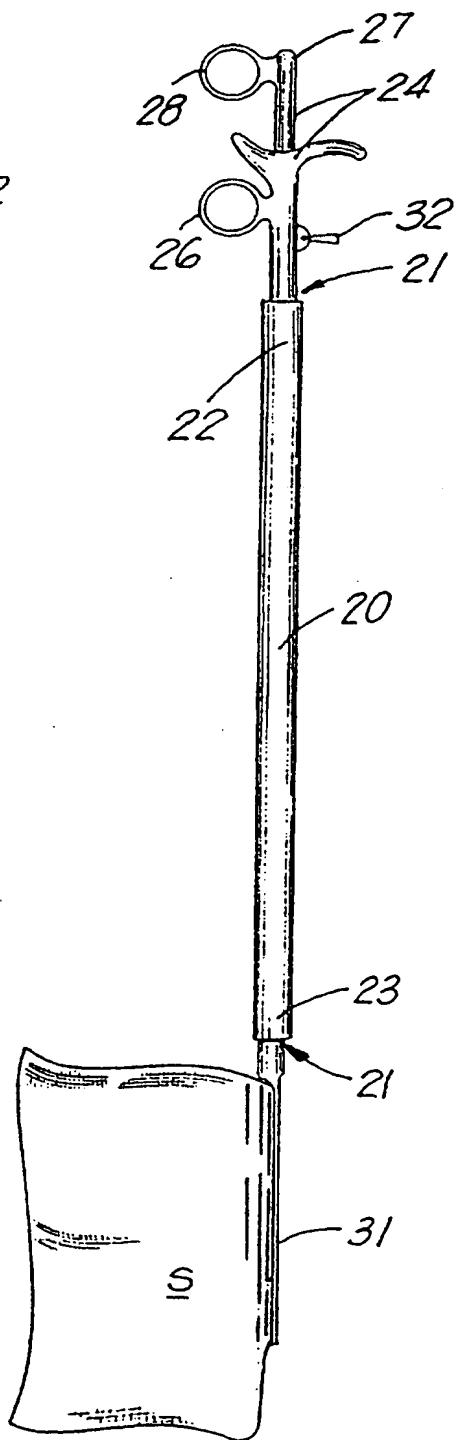
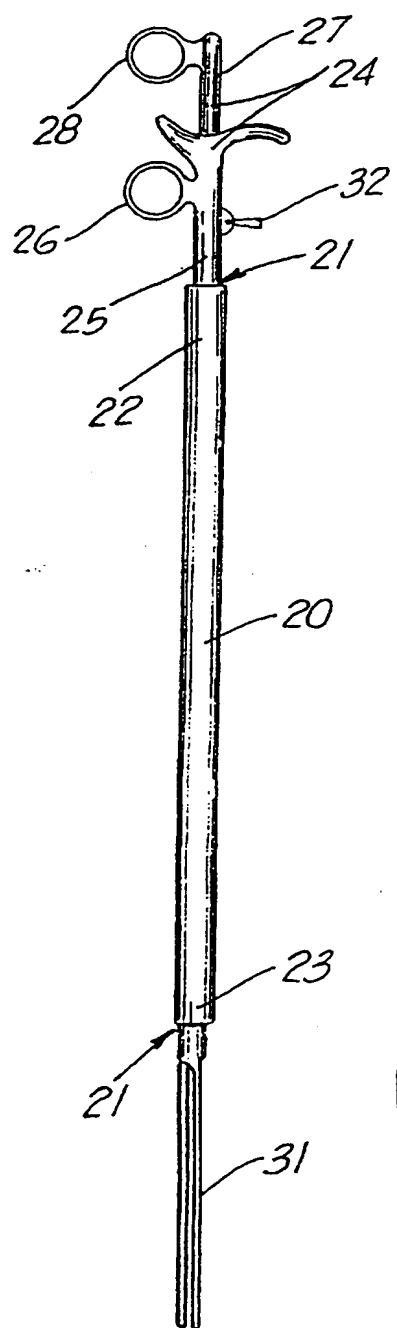
e) the instrument body being elongated enough so that the surgeon can position the jaws in the patient's abdominal cavity and wherein the jaws can be opened and closed with the operator when so positioned inside the patient's abdominal cavity.

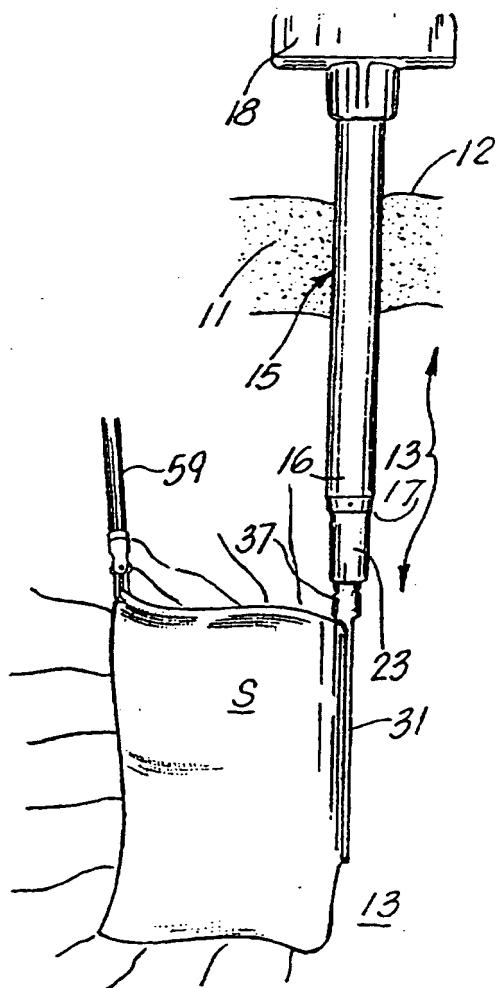
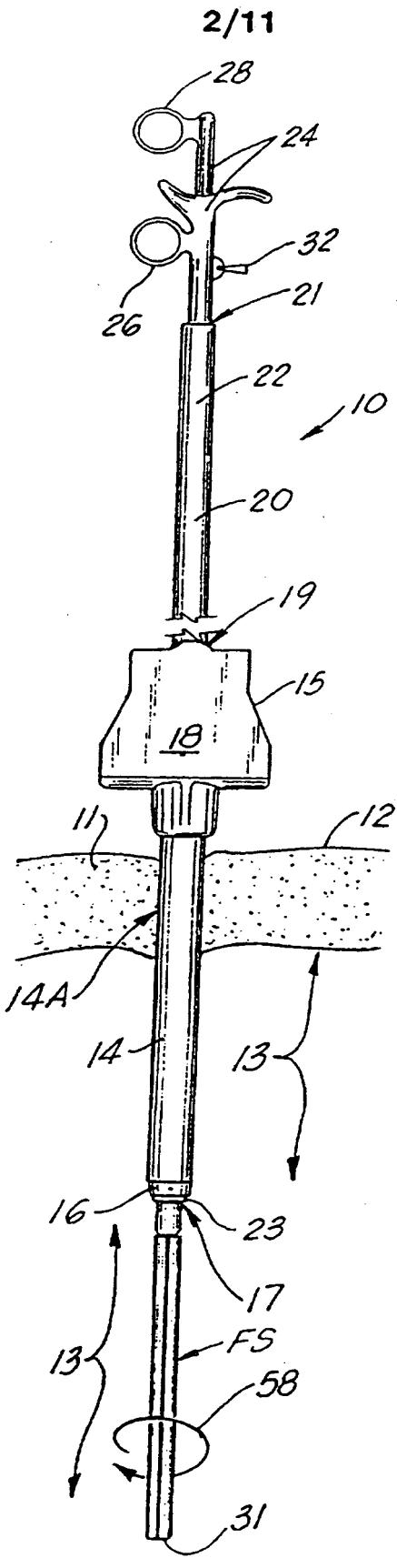
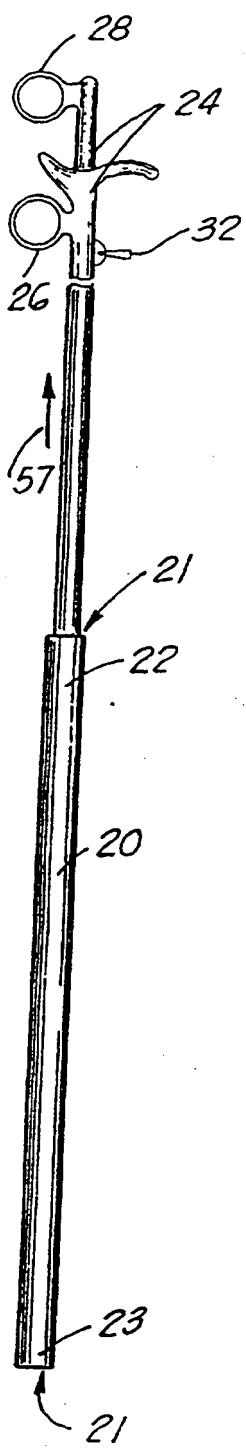
25 71. The laparoscopy instrument of claim 70 further comprising an envelope that holds the surgical sheet like article.

72. The laparoscopy instrument of claim 70 wherein the sheet article has a memory that prevents or hinders unrolling during surgery and further comprising an envelope that packages the sheet like article in a flat position.

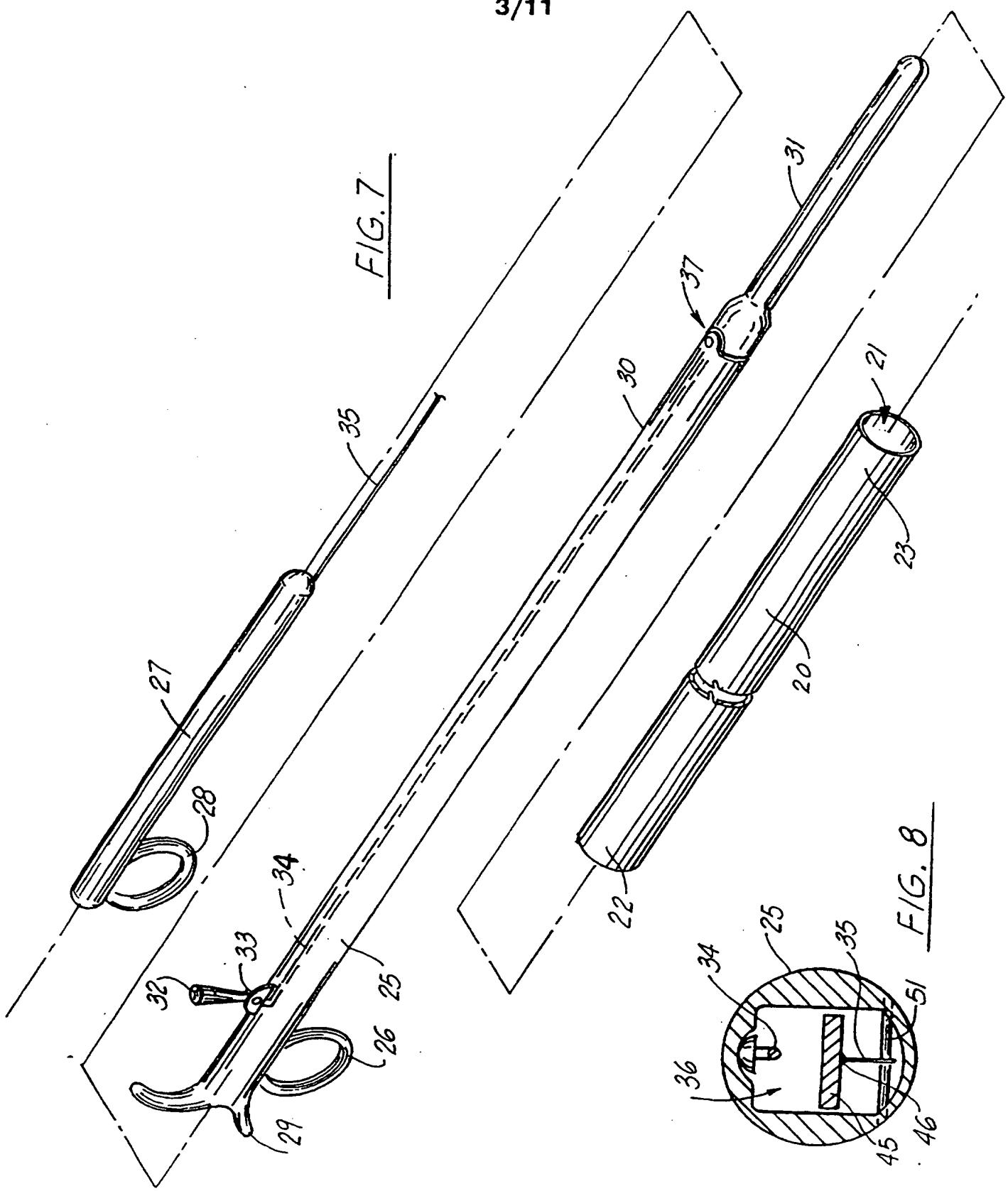
30 73. The laparoscopy instrument of claim 72 further comprising a clamp that holds the jaws in a gripping position wherein the jaws are attached to the sheet like article.

1/11

FIG. 1FIG. 2FIG. 3



3/11

FIG. 7FIG. 8

4/11

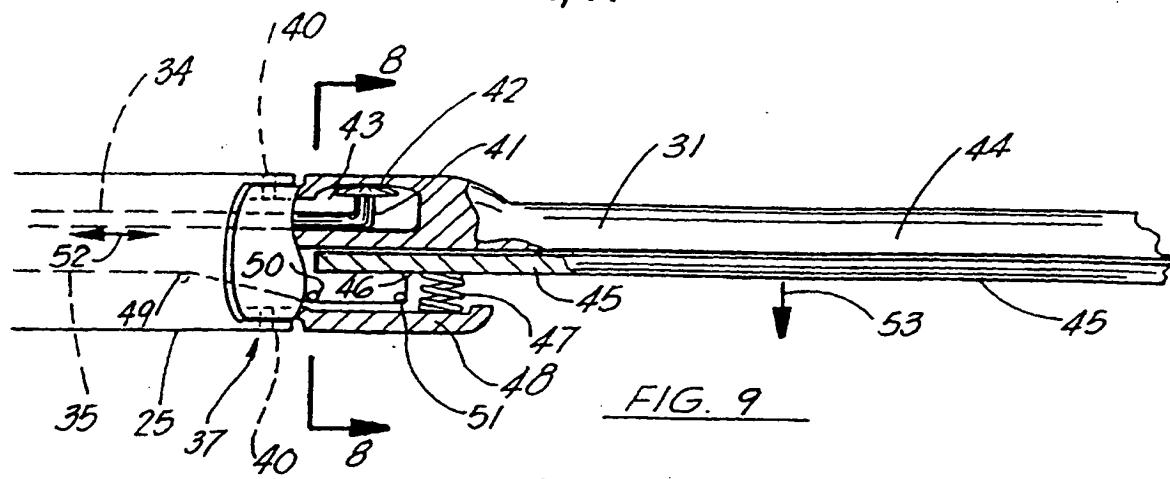


FIG. 9

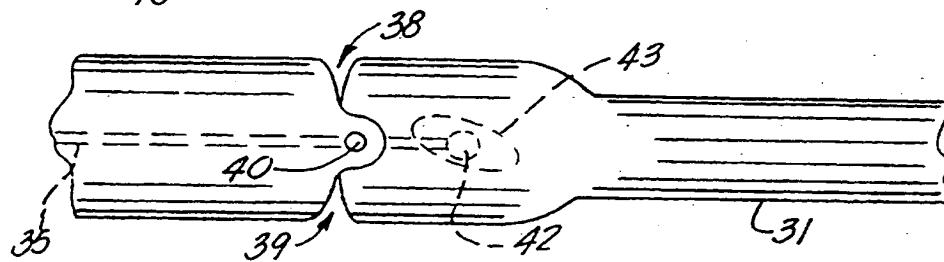


FIG. 10

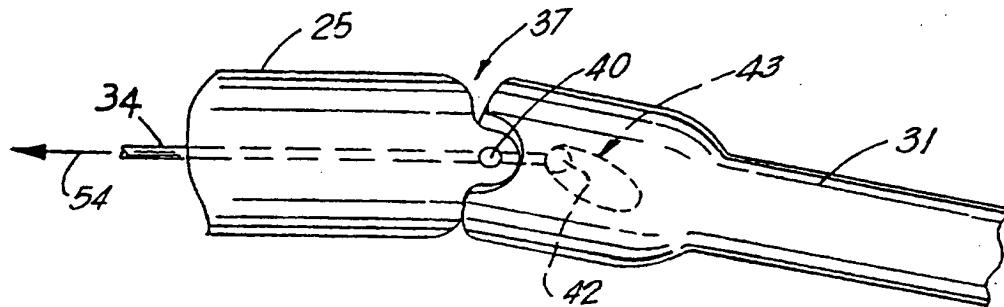


FIG. 11

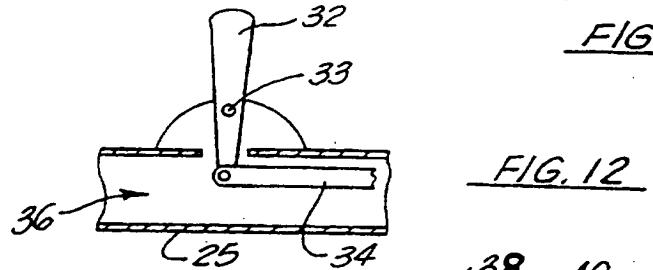


FIG. 12

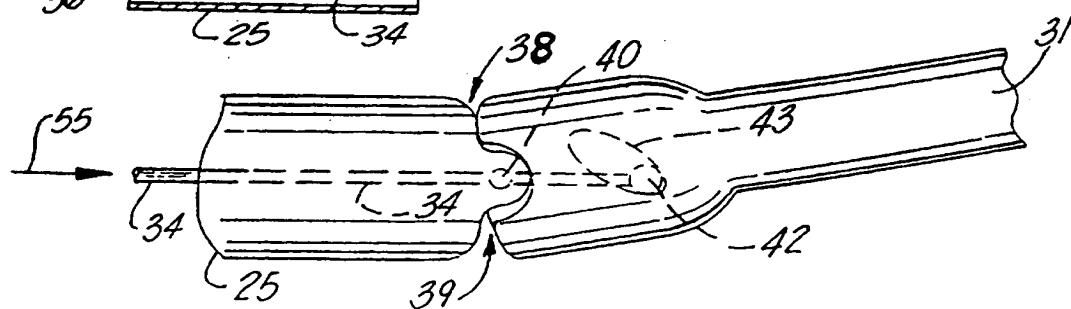
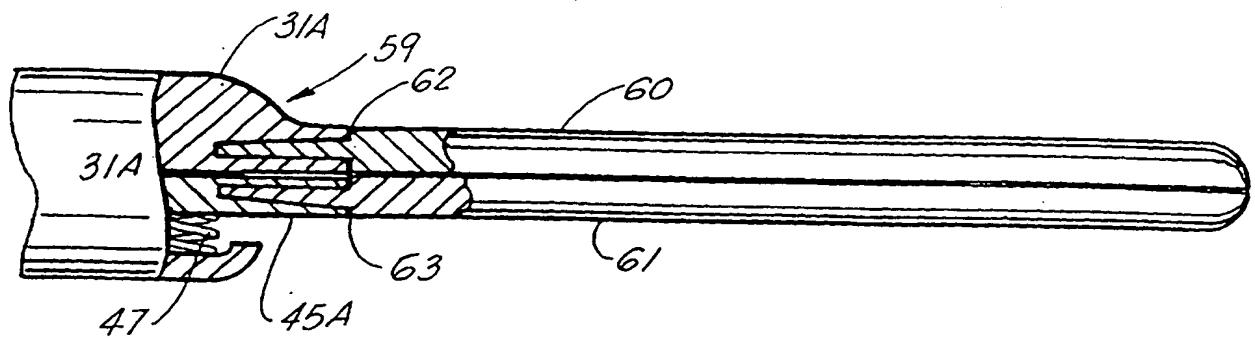
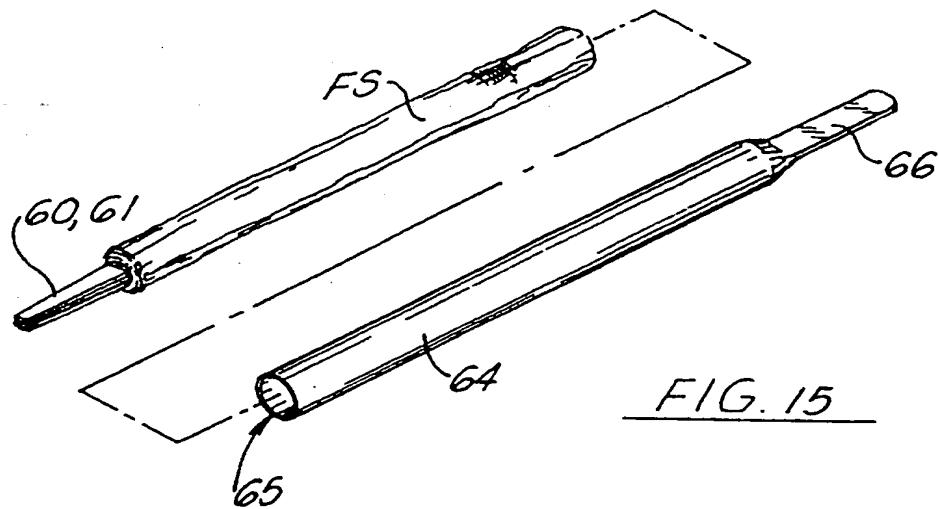
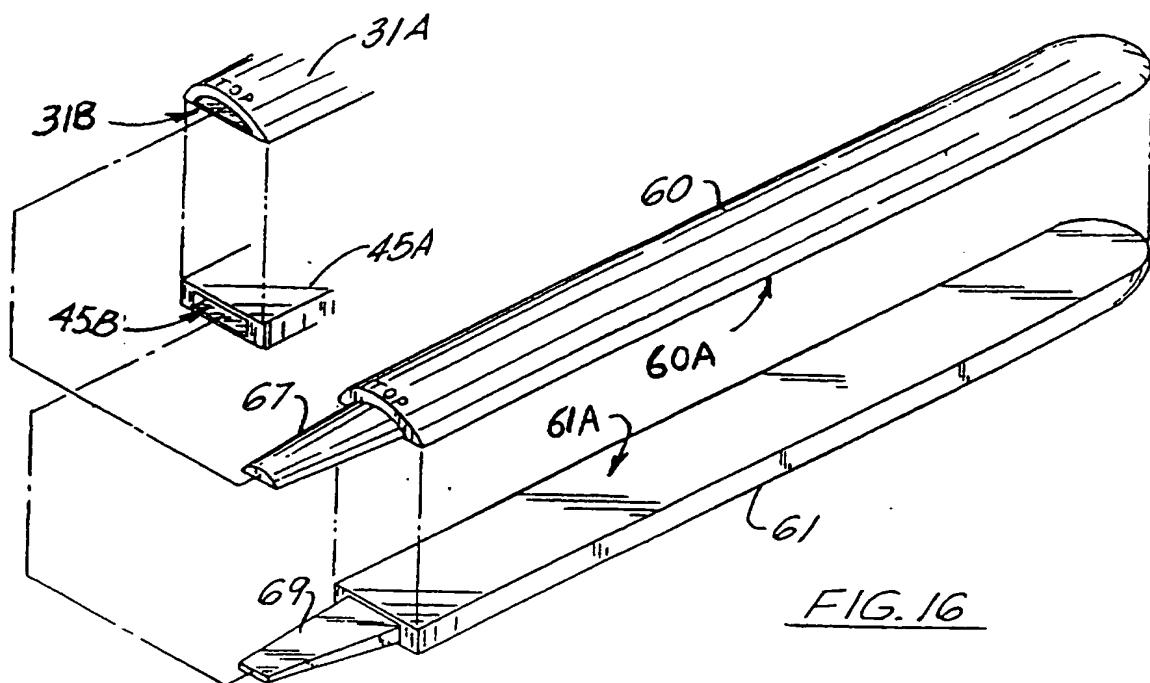
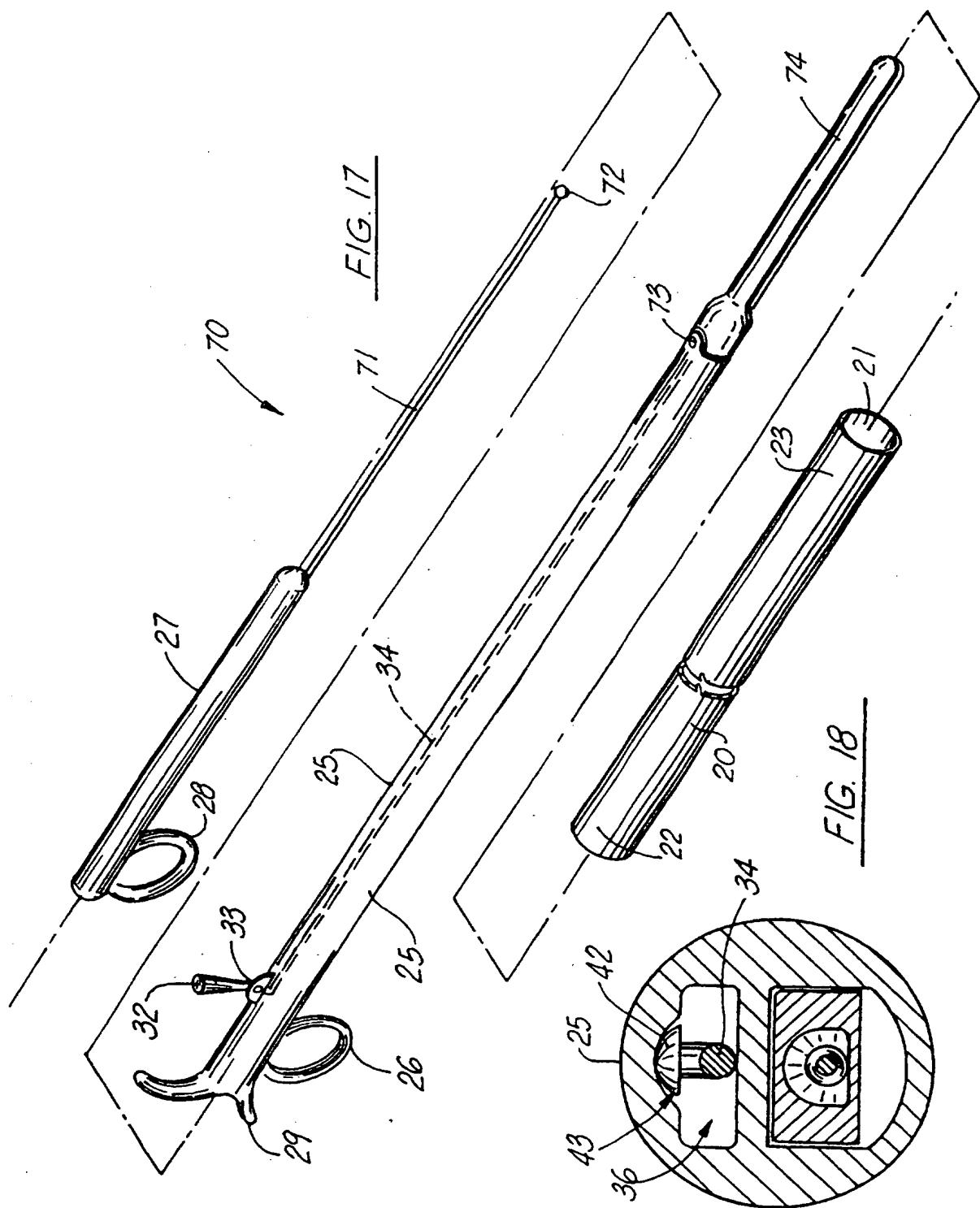


FIG. 13

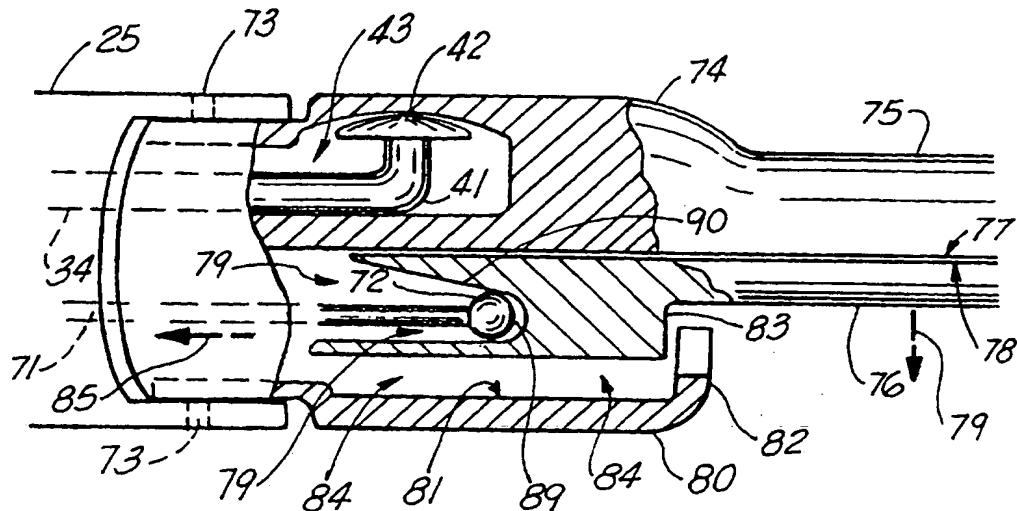
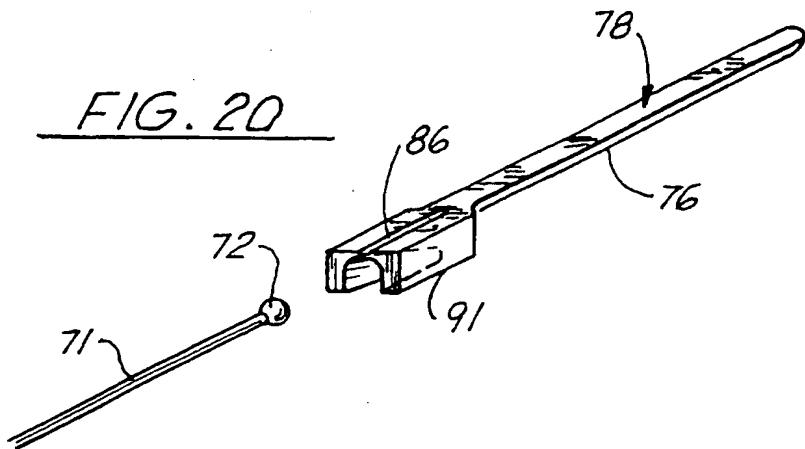
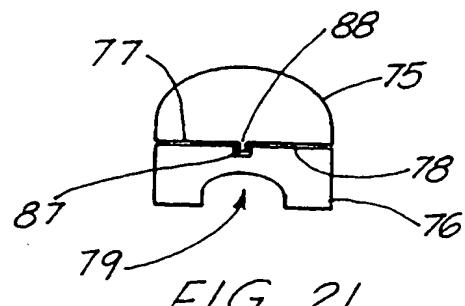
5/11

FIG. 14FIG. 15FIG. 16

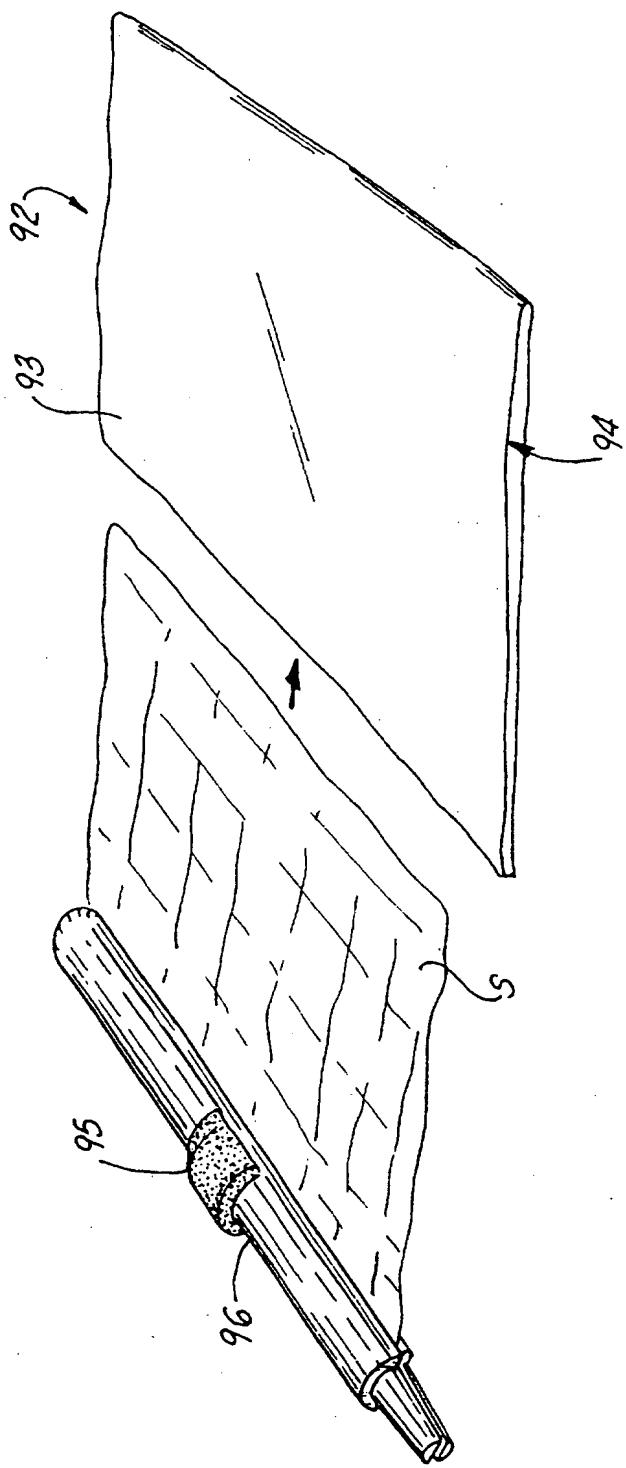
6/11



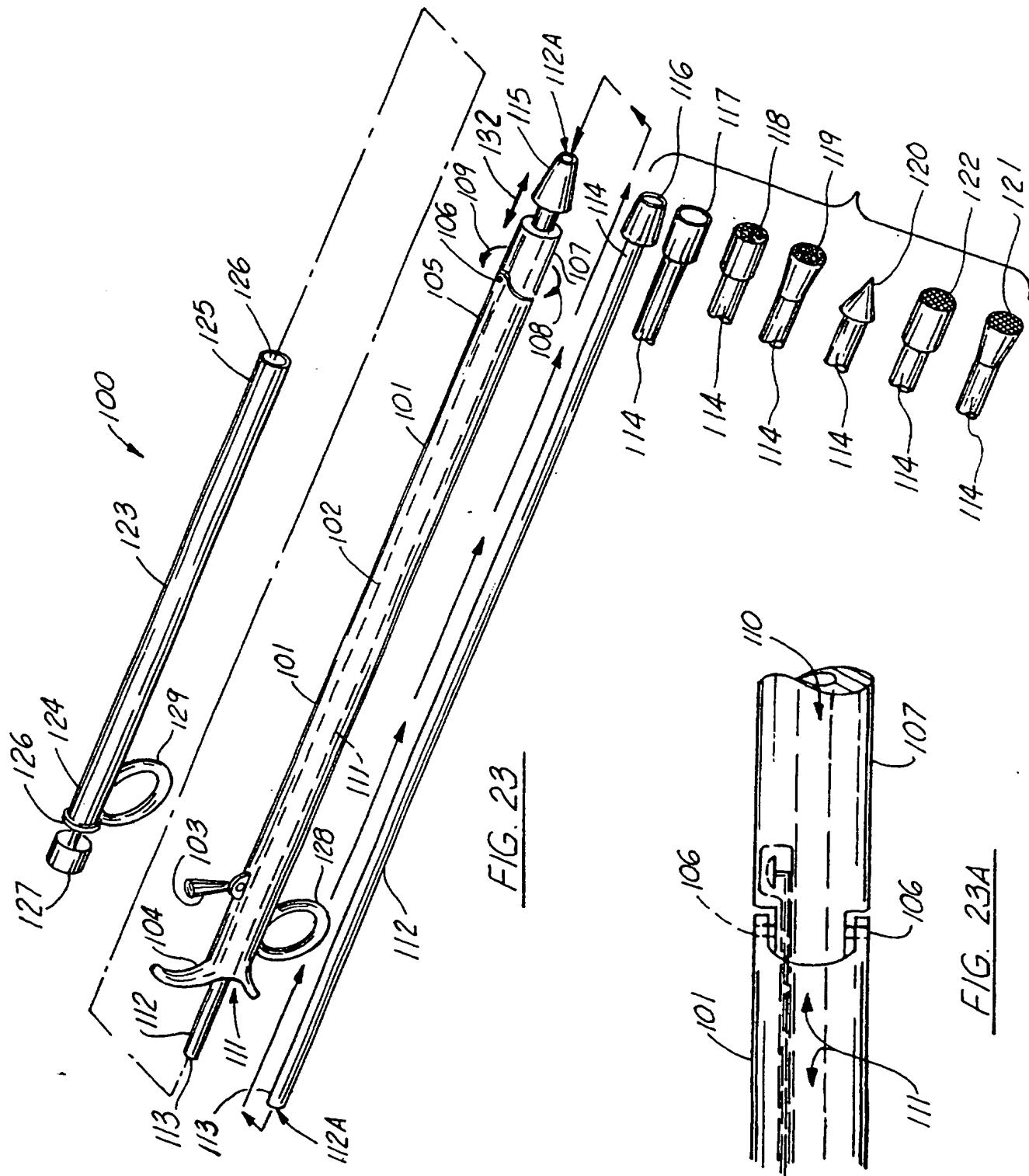
7/11

FIG. 19FIG. 20FIG. 21

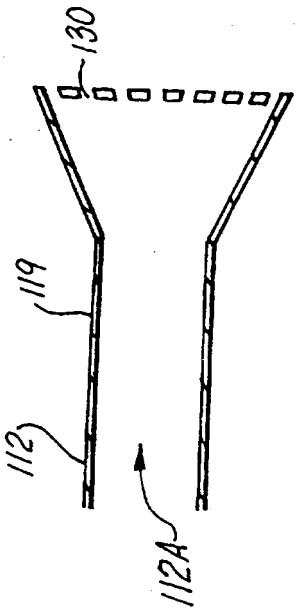
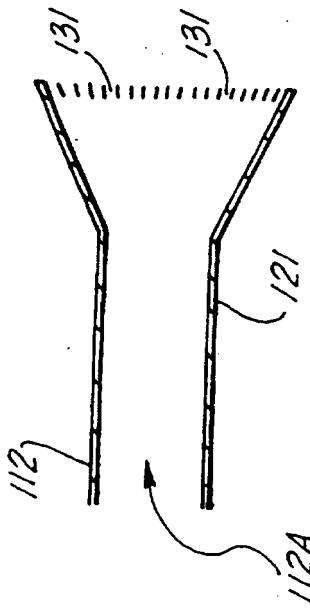
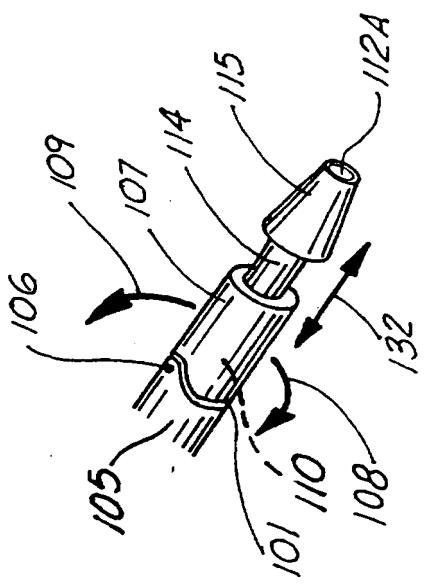
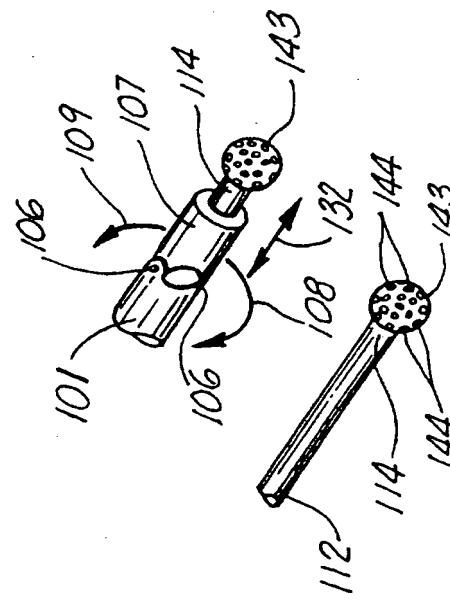
8/11



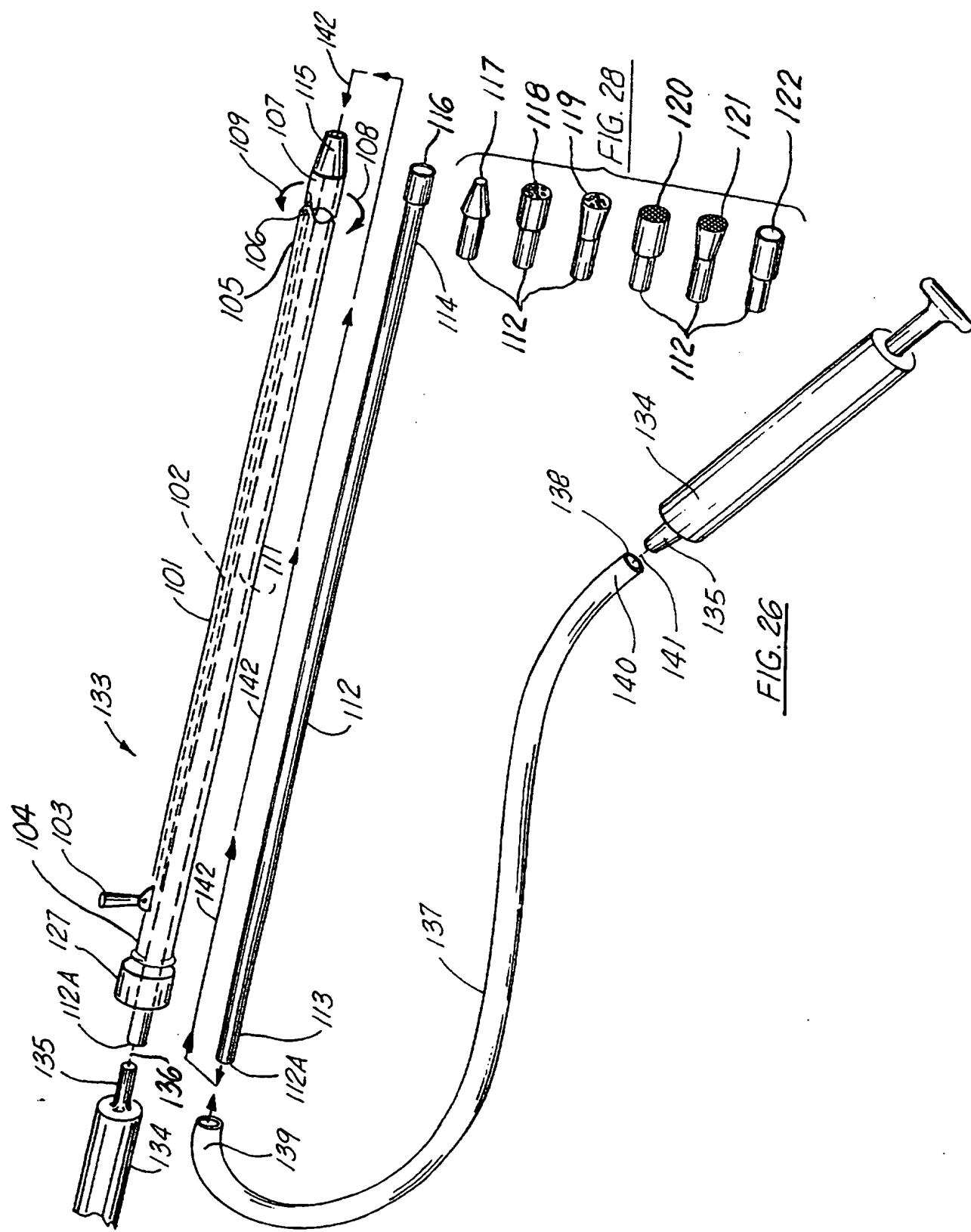
9/11



10/11

FIG. 24FIG. 25FIG. 27AFIG. 27B

11/11



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/05397

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) A61M 5/00

US CL 606/001, 151; 604/13, 15, 264

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 601/160-163,166,169; 604/13,15,27,28,36,39,43-45,48,49,51,93,94,181,187,239,264; 128/200,14,200,18,200,19;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-------------------------------|
| X | US 5,125,910 A (FREITAS) 30 June 1992, abstract, col. 1, lines 26-42, figure 1. | 1,3,4,6-11,14-22,24-40, 43-50 |
| X, P | US 5,533,986 A (MOTTOLA et al.) 09 July 1996, entire document. | 1,3,4,6-11,14-22,24-40,43-50 |
| Y | US 5,263,927 A (SHLAIN) 23 November 1993, col. 1, lines 19-25, lines 24-30, figures 1-3. | 51,52,54-73 |
| Y | US 5,304,187 A (GREEN et al.) 19 April 1994, col. 1, lines 15-20. | 51,52,54-73 |

 Further documents are listed in the continuation of Box C.

See patent family annex.

| | |
|--|--|
| Special categories of cited documents: | |
| "A" | document defining the general state of the art which is not considered to be of particular relevance |
| "E" | earlier document published on or after the international filing date |
| "I" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) |
| "O" | document referring to an oral disclosure, use, exhibition or other means |
| "P" | document published prior to the international filing date but later than the priority date claimed |
| "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "&" | document member of the same patent family |

Date of the actual completion of the international search

07 JULY 1997

Date of mailing of the international search report

25 JUL 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer

STEPHEN HUANG

Telephone No. (703) 308-3399

Form PCT/ISA/210 (second sheet)(July 1992)*

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

This Page Blank (uspto)